ENGLISH

ENGLISH - User Manual

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1. Introduction

The **Baby DOPPLEX® 4000** fetal monitor (**BD4000)** provides a unique combination of options. Incorporating all the standard functions of conventional cardiotocographs (CTGs), it provides the most cost-effective and flexible approach to fetal monitoring.

The **BD4000** model is available in standard form for antepartum monitoring. Additionally, plug-in options are available to provide intrapartum and twins capability. These options are available separately and can be added retrospectively, simply by plugging them in when required.

Interface cables are available to connect the BD4000 to external equipment for data exchange. Options include:

Connection to electronic viewing and archiving systems.

Connection to Vital Signs monitors for recording maternal data on the CTG print-out

Connection to fetal $Sp0_2$ monitors for recording $FSp0_2$ on the CTG print-out.

The standard unit is supplied complete with:

BD4000 main unit

Ultrasound transducer

External Contractions (toco) transducer

Patient Event Marker

Printer Paper (2 packs)

Gel (1x 250ml bottle)

Latex Free Transducer Belts (x2)

Mains cable

User Manual

Fetal Monitor Detector

The standard unit includes an automatic fetal movement detection system. This provides an indication of movement, detected from the low frequency components of the Doppler signal.

☞ *It should be noted that this system will be triggered by any low velocity movement above a set threshold (user adjustable) and may arise from other movements, such as transducer or maternal movement.*

Upgrade Options

The following additional options may have been supplied with your unit or can be ordered separately to upgrade your unit:

Intrapartum upgrade

Comprising:

- Active leg plate transducer
- Leg Plate belt (2 off)
- ECG gel

Twins upgrade

Comprising:

- Interface cable (incorporating interface electronics)
- Wide Twins paper (2 packs)

☞ *The twins option requires two BD4000 main units. When interconnected, one is automatically configured as the local unit, the second as the remote unit. See the twins set-up and operation section for more details.*

Intrauterine Pressure Option

Comprises:

- Pressure sensor kit and interface module

☞ *Note that details on the Intrauterine Pressure option, are covered separately in the instructions supplied with the option kit.*

Accessories

A wide range of accessories is available for use with the **BD4000** fetal monitor including:

- Trolley - optionally available with 2 shelves for twins system
- Wall mounting bracket
- Interface cables - refer to 'Data Interface' section for details
- Consumables - gel, paper, belts
- Carry case

2. Recommended Clinical Applications

The **BD4000** is intended for use in all conventional fetal monitoring applications.

DO use **BD4000** for:

Antenatal monitoring in the hospital, health clinic, home or community

Hospital admission CTG's

Labour monitoring - use of external ultrasound is recommended in all monitoring applications except where:

Ultrasound is unable to provide reliable continuous traces,

AND

Clinical risk factors / indications justify the use of invasive scalp clips for FECG monitoring.

DO NOT use **BD4000** for:

Underwater monitoring in waterbirth management - a range of **Aqua Dopplex**® Dopplers are available for this

Monitoring in any environment where the patient, user or unit is likely to come into contact with water.

Guidelines on the use of BD4000:

Fetal monitors provide just one indicator of fetal condition. This should be assessed as part of an holistic approach to obstetric care together with other factors. A complete assessment must be made before appropriate action is taken.

Scalp clips are invasive and their use carries a degree of risk, including increased risk of cross-infection. They should only be used under the conditions outlined above. The decision to use them remains the responsibility of the clinician.

Ultrasound monitoring should be performed in accordance with current guidelines. The ALARA guideline (AIUM) recommends that ultrasound exposure should be kept As Low As Reasonably Achievable.

3. Product Description

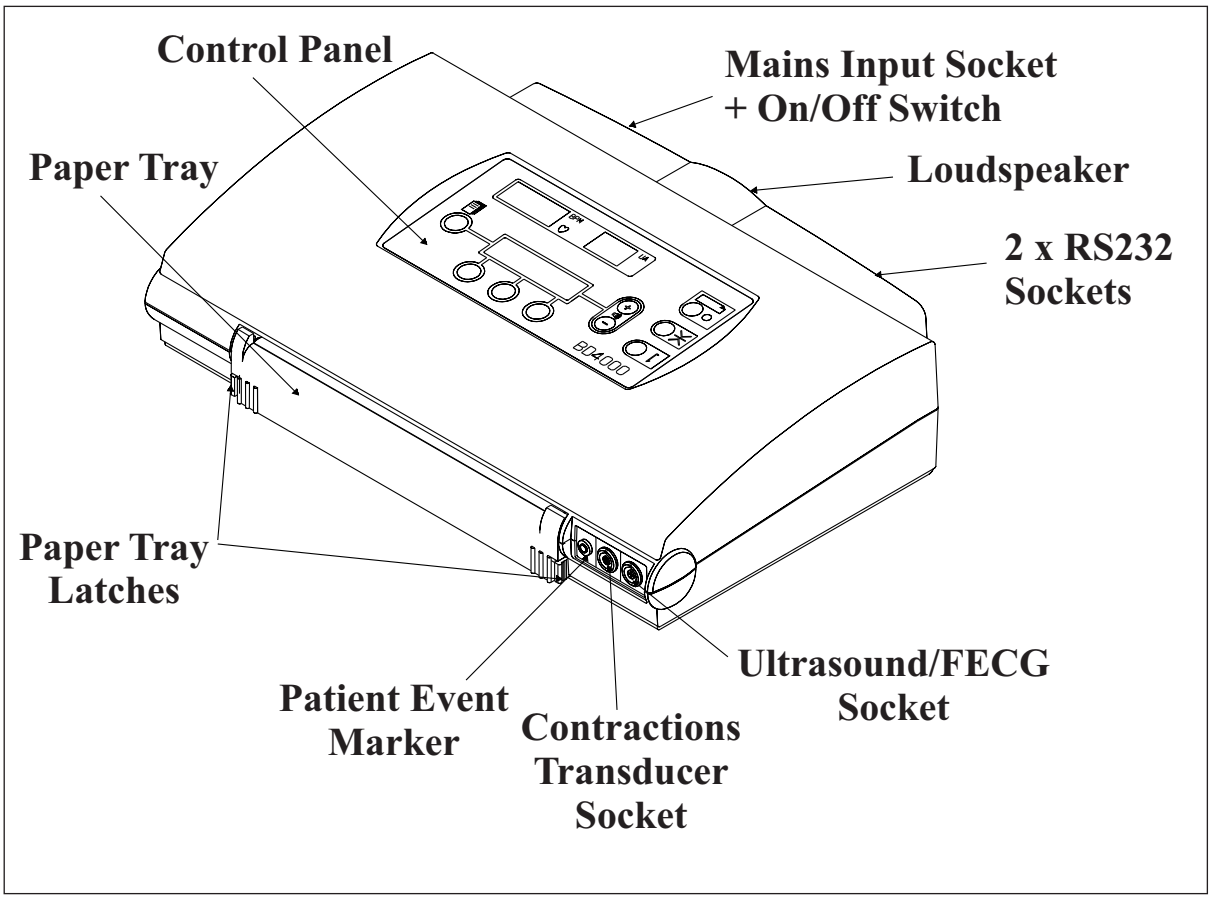


Figure 1 BD4000 Front View

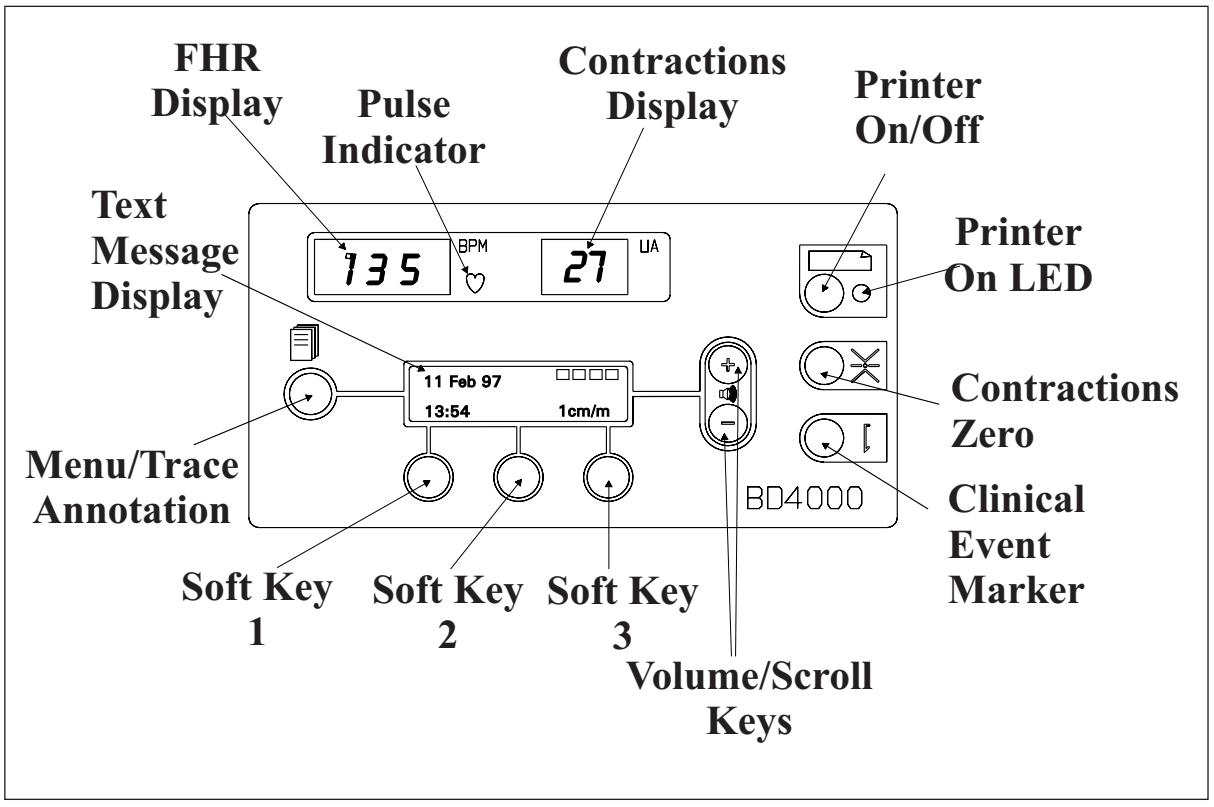


Figure 2 BD4000 Control Panel

4. Setting Up the BD4000

Mains Connection/ Switching On

Connect the unit to a suitable mains power source using the cable supplied. The **BD4000** will operate at any a.c. mains voltage in the range 100 to 250V,
at 50 or 50Hz. No adjustment is necessary.

Switch the unit on.

Paper Loading

Open the paper tray by simultaneously depressing the latches at each end, as shown in Fig. 3. Slide the paper tray forwards. Note that the LCD text display shows '**PAPER TRAY OPEN**'.

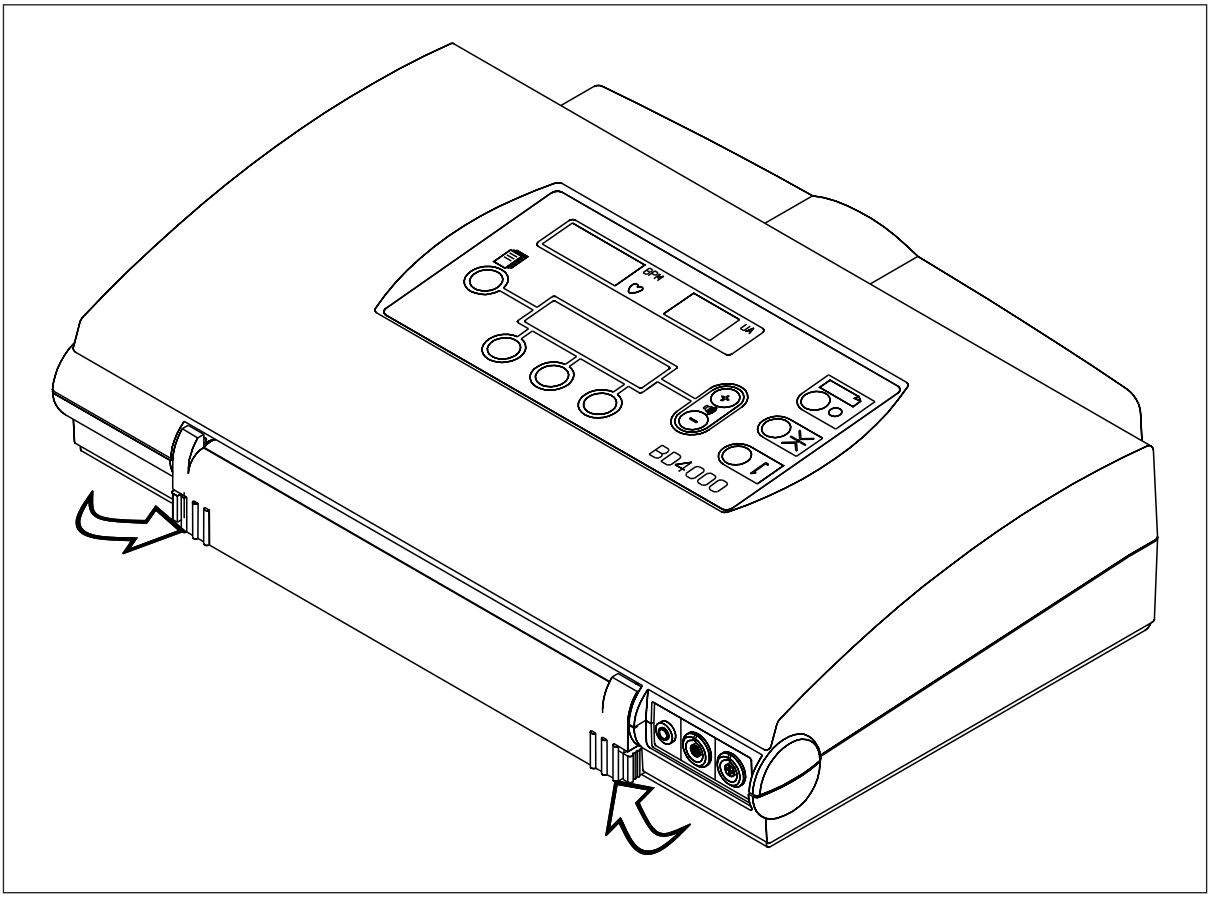


Figure 3 Paper Loading Instructions

Twins

Special wide paper, supplied with the Twins option pack, provides optimal presentation of the two traces on separate, full range, FHR scales, together with contractions, movement and event marker data.

Alternatively, using standard paper, the two traces are superimposed on the standard FHR scale.

Adjusting Paper Width

Ensure that the adjustable paper guide is set to the correct position for the paper.

☞ *Note that this can only be adjusted, by sliding left/right, when the paper tray is fully open.*

Ensure that it is located in the appropriate position indent. The paper tray cannot be closed if this is not located correctly.

Inserting Paper

Remove the paper pack outer film, discard the top and bottom card inserts, and insert pack into the tray. Ensure that the sensitive side is facing up. To confirm this, ensure that the pre-printed sheet numbers are visible on the right hand side of the pack (see Fig. 4). Refer to the paper loading guide in the paper tray. This guide should be left in place for future reference.

☞ *Note that the small hole in this guide must be positioned towards the front right hand side to ensure end-of-paper detection.*
A marker strip on the last few sheets of paper will indicate when the paper is about to run out. When no paper is left in the tray, the display will indicate 'END OF PAPER'.

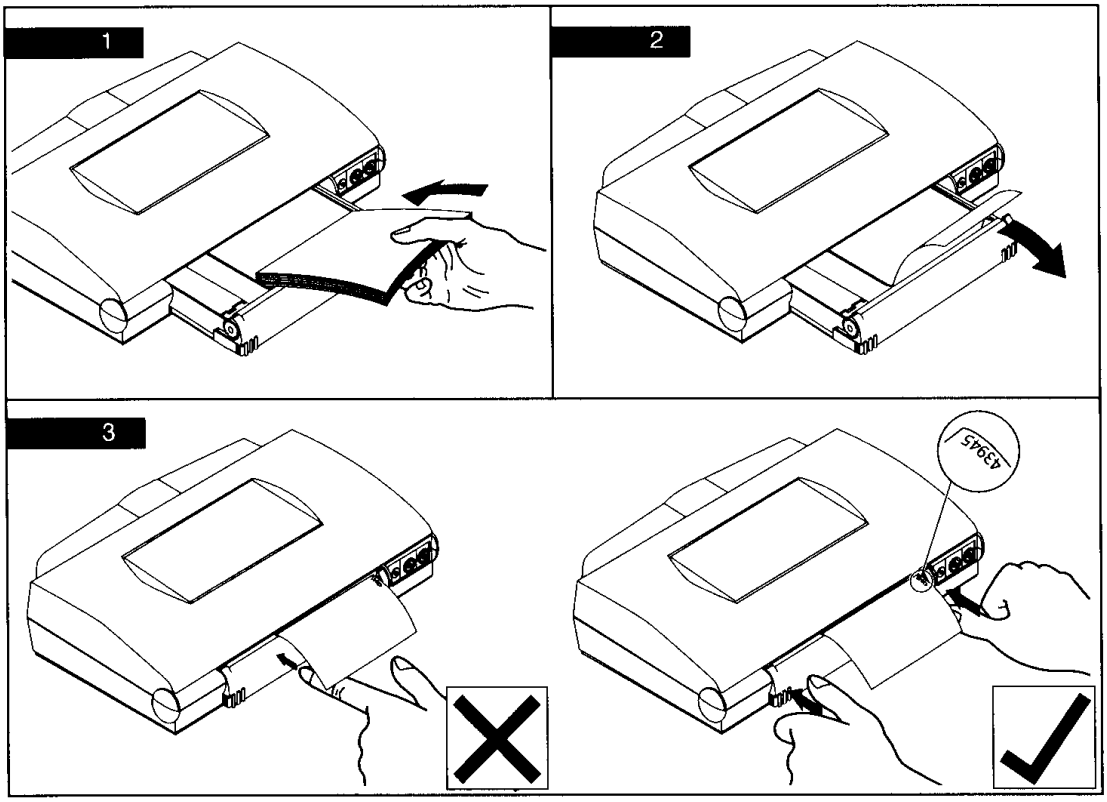


Figure 4 paper Loading Guide

Pull the top sheet out over the roller.

Using both hands, push the paper tray firmly shut.

☞ *Ensure that the latches at both ends are securely locked. (See Fig. 5). If the tray is not properly latched shut at both ends, the unit may not print, or poor print quality may be observed.*

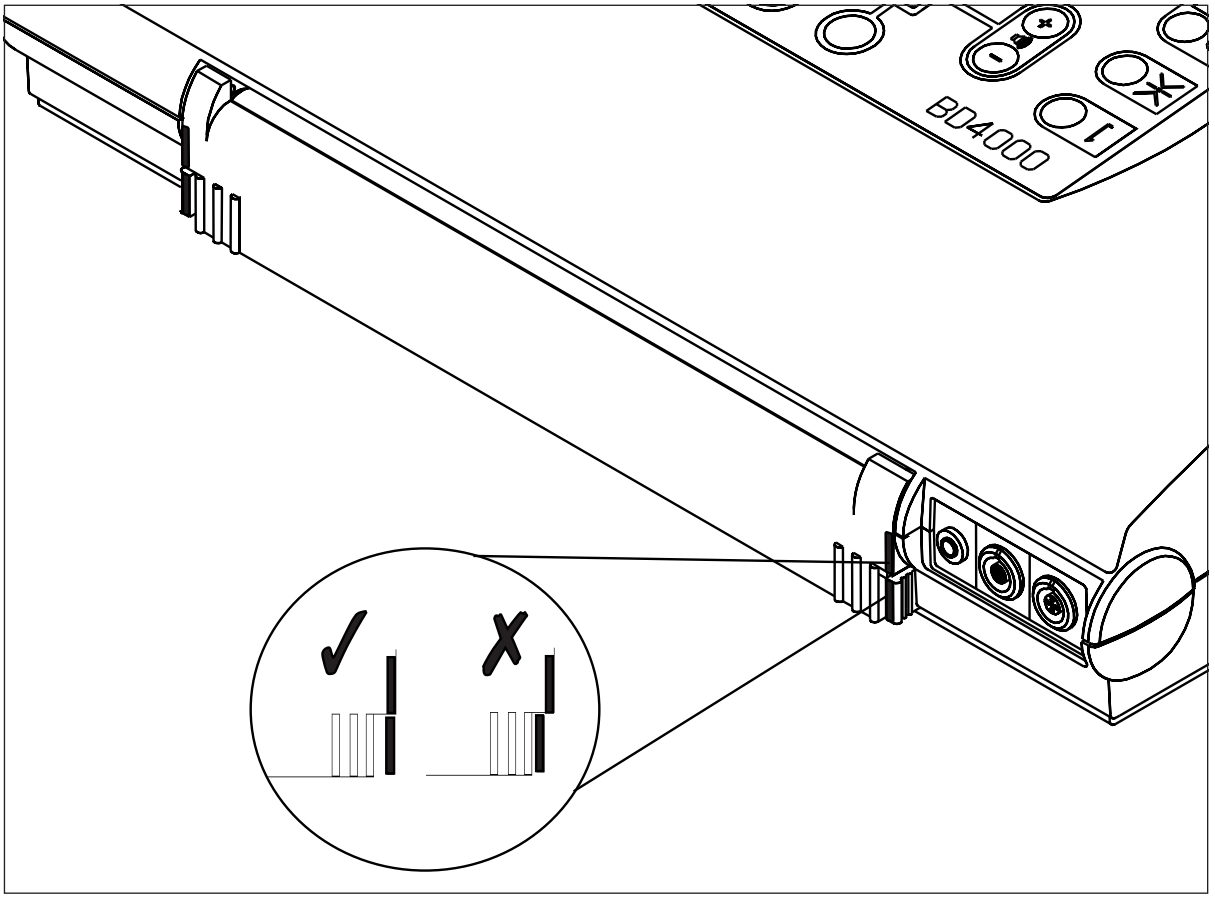


Figure 5 Paper Tray Firmly Shut

Use only the correct paper packs supplied by Huntleigh Healthcare. Paper quality varies widely. Use of inferior quality paper may result in poor trace quality, may damage the unit and invalidate the warranty.

CAUTION

Do not use pre-printed paper designed for use in other fetal monitors - the registration of the trace to the pre-printed scale will not be accurate

System Set-Up Option

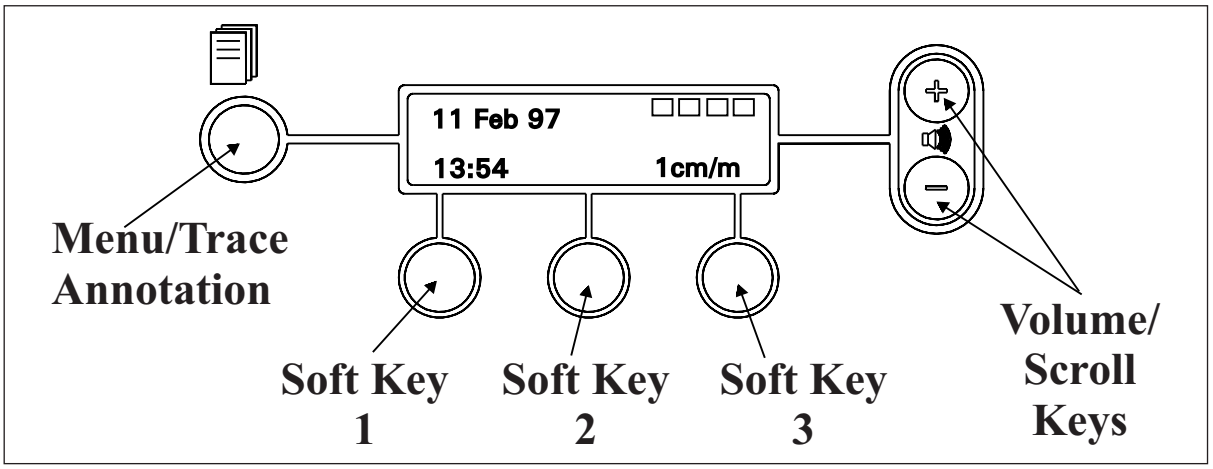


Figure 6 User Selectable Options

The following user selectable options can be selected, using the keys on the control panel (refer to Fig. 6).

These settings should be set as required when the unit is first installed. The saved settings will be retained when the unit is switched off.

Fetal movement detector

Chart speed - select 1, 2 or 3 cm/min

Time

Date

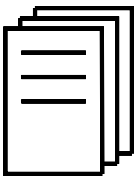
Grid (beats/cm) - select 20 or 30 bpm/cm

Language

Alarms

External Data

Set-up Procedure



Ensure the unit is not printing - the 'Printer On' LED must not be lit.

Press the 'Menu' button. The display will show 'User Setup' with flashing arrows pointing to the Volume/Scroll keys. Use either key to scroll through the options listed above. Each key press will move on to the next option, moving either up ('+' key) or down ('-' key) through the options. When the desired option is displayed in the text display, use the 3 keys below the display to adjust the option as required. These operate as 'soft keys' where their function is defined by labels in the text display, as described below:

Fetal Movement Detector

Soft key 1 : Toggle function off/on.
Soft key 3 : Increment trigger threshold.
Soft key 2 : Decrement trigger threshold.

☞ *Notes:*

1. *Default setting is 40%*
   (Recommended setting for normal use.
2. *This function is intended for antenatal use only and should be disabled during labour monitoring.*
3. *For reliable operation, the ultrasound transducer should be correctly fitted with the supplied belt. Do not hand hold as movement of the transducer may falsely trigger the detector.*
4. *Function not available in FECG mode.*

Chart Speed

Soft key 1 : 1 cm/min (standard European setting).
Soft key 2 : 2 cm/min.
Soft key 3 : 3 cm/min (standard USA setting).

Time

Soft key 1 : Select hours/minutes.
Soft key 2 and 3 : Increment/decrement the selected value as required.

Date

Soft key 1: Selects Day/Month/Year.
Soft key 2 and 3 : Increment/decrement the selected value as required.

Grid (beats/cm)

Soft key 1 : 20bpm/cm (standard European setting).
Soft key 3 : 30bpm/cm (standard USA setting).

Language

Soft key 3 : Selects the desired language.

Alarms

Applicable from Serial Number: 614-98-B-0407

Loss of Contact (LOC) alarm

Detects when loss of contact (drop-out) occurs for a percentage (%LOC) of a preset time period. Both the percentage threshold and time are user selectable. The alarm can be disabled or can operate in silent or audio modes.

- Time range : 0 to 20 minutes (default setting - 10 minutes)
- %LOC range : 0 to 99 (default setting – 50%)
- Modes
  - *Off – alarm function is disabled (default mode)*
  - *Silent – alarm condition indicated on LCD display and print-out*
  - *Audio – display and print-out as per Silent mode accompanied by bleeping audio tone*

Set-up:

Enter set-up mode and use the 'Volume/Scroll' keys to scroll through the menu to select 'LOC.alarm ...'

Soft key 1 : Selects time/%/mode
When time/% selected:
Soft keys 2 & 3: Increment/decrement value
When mode selected:
Soft key 3 : Selects Off/Silent/Audio

Tachycardia alarm

Detects when fetal heart rate (FHR) has remained above a user selectable threshold, for a user selectable time. The alarm can be disabled or can operate in silent or audio modes.

- FHR threshold range: 150 – 200 bpm (default setting – 180bpm)
- Time range: 0–20 mins (default setting –10 minutes)
- Modes
  - *Off – alarm function is disabled (default mode)*
  - *Silent – alarm condition indicated on LCD display and print-out*
  - *Audio – display and print-out as per Silent mode accompanied by bleeping audio tone*

Set-up

Enter set-up mode and use the 'Volume/Scroll' keys to scroll through the menu to select 'Tach.alarm ...'

Soft key 1 : Selects time/rate/mode
When time/rate selected:
Soft keys 2 & 3: Increment/decrement value
When mode selected:
Soft key 3 : Selects Off/Silent/Audio

Bradycardia alarm

Detects when FHR has remained below a user selectable threshold, for a user selectable time. The alarm can be disabled or can operate in silent or audio modes.

- FHR threshold range : 50 - 120 bpm (default setting – 100bpm)
- Time range: 0–20 mins (default setting –10 minutes)
- Modes
  - *Off – alarm function is disabled (default mode)*
  - *Silent – alarm condition indicated on LCD display and print-out*
  - *Audio – display and print-out as per Silent mode accompanied by bleeping audio tone.*

Set-up:

Enter set-up mode and use the 'Volume/Scroll' keys to scroll through the menu to select 'Brad.alarm ...'

Soft key 1 : Selects time/rate/mode
When time/rate selected:
Soft keys 2 & 3: Increment/decrement value
When mode selected:
Soft key 3 : Selects Off/Silent/Audio

Clearing an alarm

To reset the alarm following an alarm condition, press softkey 2. The alarm remains enabled and will detect any subsequent alarm conditions as per the selected time / threshold settings.

A marker will be printed on the print-out to log when the alarm is reset.

NOTES:

1. *The volume of the alarm bleep (when enabled) is set independently to a factory default level, ensuring that alarms will be heard even when the user adjustable volume level is turned down. When the alarm is reset, the volume level is restored to the user set level.*
2. *Under no circumstances must these alarm features be relied on for monitoring the patient. Normal clinical practice with regular visual checking of the CTG trace must be maintained.*
3. *In twins mode, alarms can be independently set on each unit (disconnect twins cable from remote unit to change remote settings). Alarm conditions on either unit will be displayed and printed out on the local unit (alarm identified as FHR1(local) or FHR2 (remote)). Alarms in either unit are cleared by pressing soft key 2on the local unit.*

External Data

Applicable from Serial Number: 614AX0201600-02 (software issue 71441).

BD4000 can be configured to receive data from a range of external monitoring devices. Received data is printed on the CTG print-out.

Maternal Vital Signs monitoring.

Maternal heart rate can be presented either as numeric data printed at regular intervals or as a continuous trace superimposed on the FHR scale.

☞ *This option is not available on all makes/models of vital signs monitors.*

Fetal Oxygenation monitoring.

$FSp0_2$ can be presented either as numeric data printed at regular intervals or as a continuous trace superimposed on the contractions (UA) scale.

- ❒ Use Softkey 1 to toggle between 'Mode' and 'Trace'.
- ❒ With 'Mode' selected, use Softkey 3 to select the make of equipment to be connected or to disable this function select 'Off'.
- ❒ With 'Trace' selected, use Softkey 3 to turn trace mode 'On' or 'Off'.

Saving Set-up Changes

When any change to the set-up is made, the change must be saved to initiate the new set-up.

Press the 'Menu' button.
The display will show 'Save changes - Yes or No'.
Using the soft keys, select 'Yes' or 'No' as required.
The unit will return to normal operation and initiate any saved changes.

☞ *Note that, during set-up, if no key presses are detected for a period of 30 seconds, the unit will return to normal operation and will restore the last saved set-up.*

5. Operation

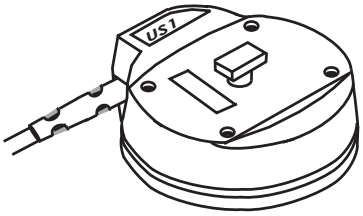
Before each monitoring session, check that system set-up is correct (date, time, chart speed, etc.) and that there is sufficient paper.

Check that the unit is not damaged in any way and ensure that cleaning procedures have been followed.

Antepartum Operation

Connecting the Transducers

Ultrasound Transducer

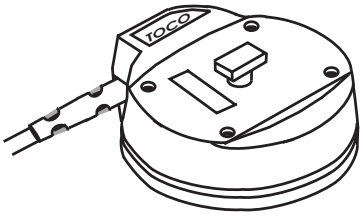


Plug the ultrasound transducer (marked ‘US1’, colour coded red) into the 'Ultrasound/FECG' socket on the front panel of the main unit.

This socket is also colour coded red. Align the red dot on the metal connector with the red dot at the top of the socket and press the connector in firmly.

Do not use excessive force.

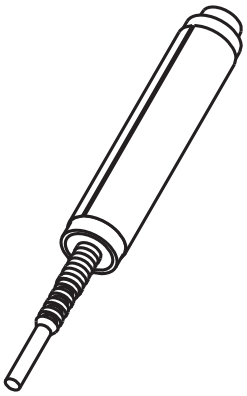
Contractions Transducer



Similarly, plug the contractions transducer (marked ‘TOCO’, colour coded blue) into the ‘TOCO’ socket on the front panel.

This is also colour coded blue.

Patient Event Marker



Plug the patient event marker into the left hand socket (3.5mm jack socket).

Ensure plug is fully inserted.

The unit is now ready for use.

Monitoring

Position the patient as required - typically in the semi-supine position and pass the elastic belts around the patient's abdomen.

Typically, the contractions transducer is positioned at the level of the fundus of the uterus, while the ultrasound transducer is positioned lower on the abdomen at the level of the fetal heart.

Ultrasound Transducer

To locate the best position for the ultrasound transducer, note the gestational age - with increasing gestational age the heart will be higher up the abdomen - and palpate. Best results will be achieved with the transducer placed over the fetus's upper back over the left scapula.

Gel

Apply sufficient gel to the abdomen (or to the face of the transducer) to ensure good contact over the full face of the transducer.

Apply the transducer by hand with firm pressure to maintain contact.

Locate Fetus

Adjust the position for the best signal. For best result, position the transducer to detect fetal heart sounds, not umbilical sounds. Note that umbilical sounds will be at the fetal heart rate but do not contain the characteristic 'slapping' valve sounds heard from the heart itself.

Check Signal

Confirm the signal is fetal by comparing the rate with the maternal rate. The fetal heart rate is typically about double the maternal rate.

Volume

Adjust the audio volume using the '+' & '-' keys as required. While either key is pressed, the display will show volume level setting in the form of a bar-graph.

Belt Attachment

Attach one end of the belt to the transducer by engaging one of the holes in the belt over the button on the top of the transducer. Keeping the transducer in position, tension the other end of the belt and engage the belt over the button, ensuring sufficient tension to keep the transducer in firm contact with the abdomen. Avoid over-tightening as this will cause unnecessary discomfort to the patient.

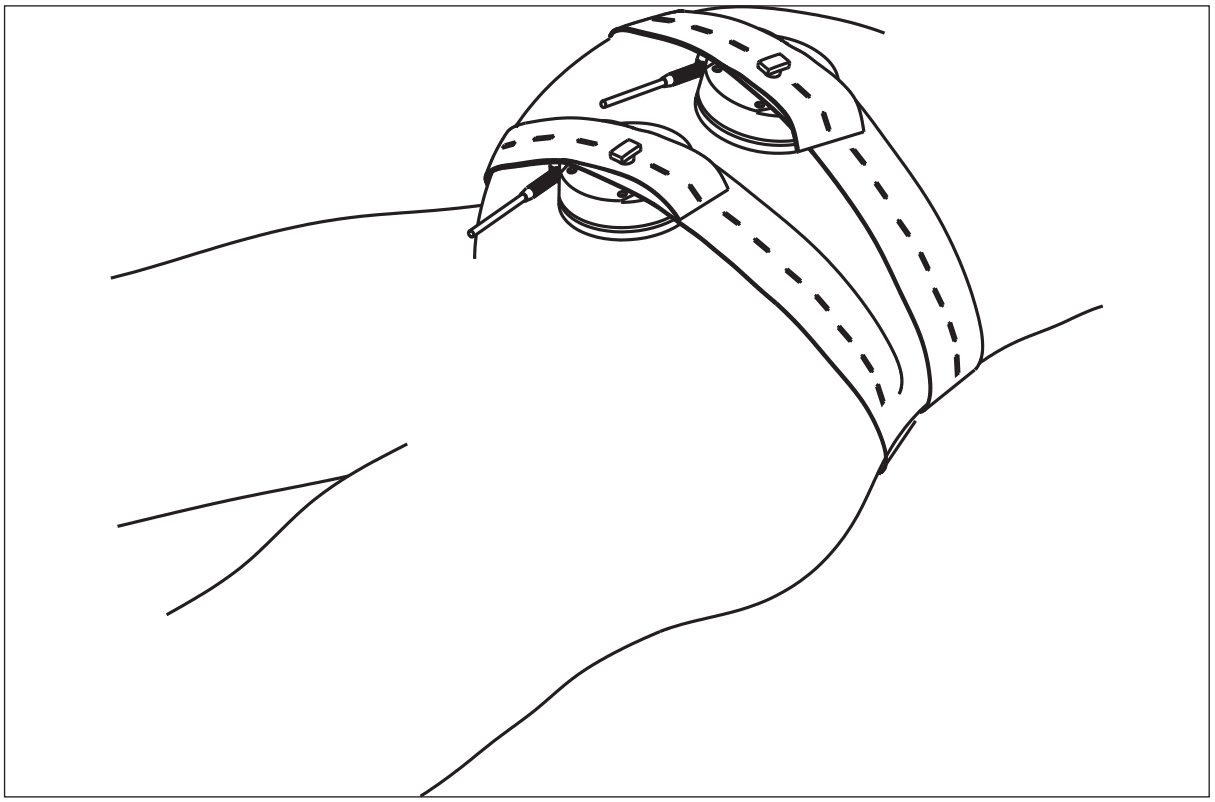


Figure 7 Transducer Belt Positioning

Re-adjust the transducer position to get the best possible signal.

If the fetus moves it may be necessary to adjust the transducer to restore signal.

Ultrasound Signal Quality indicator

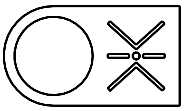
A signal quality indicator, in the form of a 4 level bar-graph, is provided in the top right hand corner of the text display. For best performance, all four elements should be showing. In the absence of signal, no elements will be seen.

Rate Display

The FHR display on the control panel shows fetal heart rate in real time.

When no signal, or poor quality signal, is present, the display will show '- - -'.

Contractions Transducer



Attach the contractions transducer in the same way as the ultrasound transducer. Do NOT use gel. Position over the fundus for best performance.

Tighten the belt to ensure good contact.

Press the contractions ‘zero’ button. This removes the pre-load due to the belt tension and sets the contractions trace to the baseline on the print-out and ‘UA’ display (set to 20% on standard units).

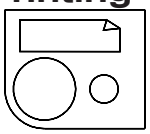
Uterine activity (UA) is displayed adjacent to the FHR display. Note that these are relative units displayed as percentage of full scale.

If the trace drops below ‘0’ the display width shows ‘L’. Check belt tension (too loose?) and re-zero.Similarly, ‘H’ will be displayed if the trace rises above the top of the scale. Check belt tension (too tight?) and re-zero.

Patient Event Marker

This should be held by the patient. Instruct the patient to press the button whenever any fetal movement is felt.

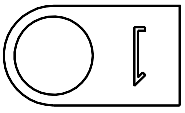
Printing



To initiate printing, press and release the printer On/Off button. The Printer On indicator will illuminate while printing is in progress. If printing does not start, check that paper is installed and that the paper tray is properly latched shut.

To stop printing, press and release the printer On/Off button. After a short fast-feed of the paper, the printer will stop. (See Fig. 8).

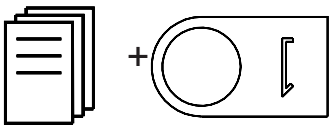
Clinical Event Marker



While printing, the clinical event marker button can be pressed to mark clinical actions. This prints a different style event mark at the top of the FHR channel to distinguish it from normal patient event marks.

Trace Annotation

While printing, the ‘Menu’ button can be used to scroll through a selection of trace annotation messages.



Select the message required on the display using the ‘Menu’ button and then press the clinical event marker button. The selected message will be printed above the FHR channel immediately after the clinical event mark. This allows clinical actions to be immediately and reliably recorded with accurate indication of timing.

☞ *The unit is supplied with a standard set of messages programmed in including: Pethidine, Oxygen, Epidural, Vaginal examination, etc. However, these can be customised to suit your requirements. Refer to your service department or supplier for further information.*

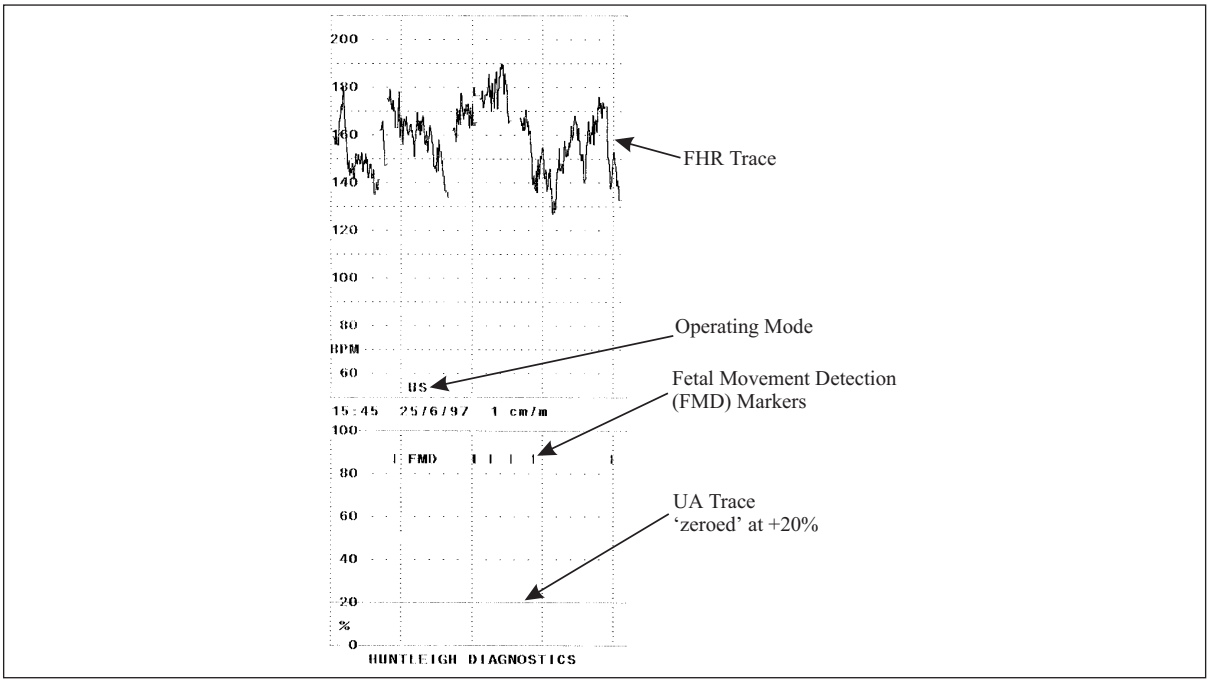


Figure 8 Single Channel Printout

Trace Interpretation The print-out is presented in internationally standardised formats (depending on set-up options selected - see **Set-Up** section) to ensure consistent presentation.

Interpretation of this information is beyond the scope of this document and should only be undertaken by experienced, qualified clinicians.

It is important to note that:

1. FHR is just one single indicator of fetal condition and that it must only be considered within an holistic approach to obstetric management.
2. In poor/difficult signal conditions, false data may be displayed/printed. Rate can be confirmed by listening to the audio signal.

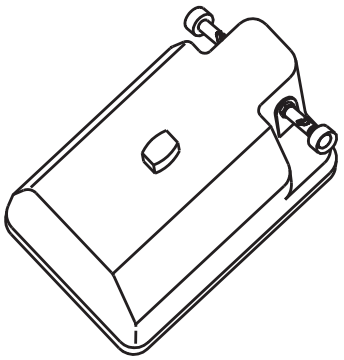
After Use The system should be carefully cleaned. Refer to **"Cleaning Instructions"** for details.

Intrapartum Operation

For external ultrasound monitoring refer to the “Antepartum Operation” section.

Connecting the Transducers

Leg Plate Transducer



Plug the leg plate (marked ‘LP1’, connector colour coded red) into the ‘US/FECG’ socket, also colour coded red on the main unit, in place of the ultrasound transducer.

This automatically reconfigures the system for intrapartum operation.

The display will show **FECG** in the top right corner.

☞ *The signal quality indicator is disabled in FECG mode. However, a ‘Leads Off’ indicator will detect loss of FECG signal.*

WARNING

The leg plate contains sensitive electronics and provides the additional electrical isolation (type BF) required for safe connection to the fetus. Inspect carefully before use for any damage as this may affect electrical isolation.
If any damage is found, do not proceed.

Contractions Transducer	Connect as for antepartum operation - refer to Antepartum Operation section.
Intra Uterine Pressure (IUP) Monitoring Option	For use in intrapartum monitoring instead of the external contractions transducer. For set-up and operation, refer to the instructions supplied with the IUP option pack.
Patient Event Marker	If required, connect as for antepartum operation - refer to Antepartum Operation section.
Fetal Movement Detector	This is intended for antenatal use and should be disabled during labour monitoring (refer to “System Configuration” section). It is automatically disabled in FECG mode.

The unit is now ready for use.

Monitoring

Leg Plate

Apply ECG gel to the metal contact plate on the underside of the leg plate module.

Pass the short belt (supplied with the Intrapartum option pack) around the maternal upper thigh.

Position the leg plate transducer on the thigh with the cable leading down towards the feet and secure the transducer in position, engaging the two ends of the belt over the button as per the other transducers (refer to antepartum section). Use only sufficient tension in the belt to ensure reliable contact is maintained.

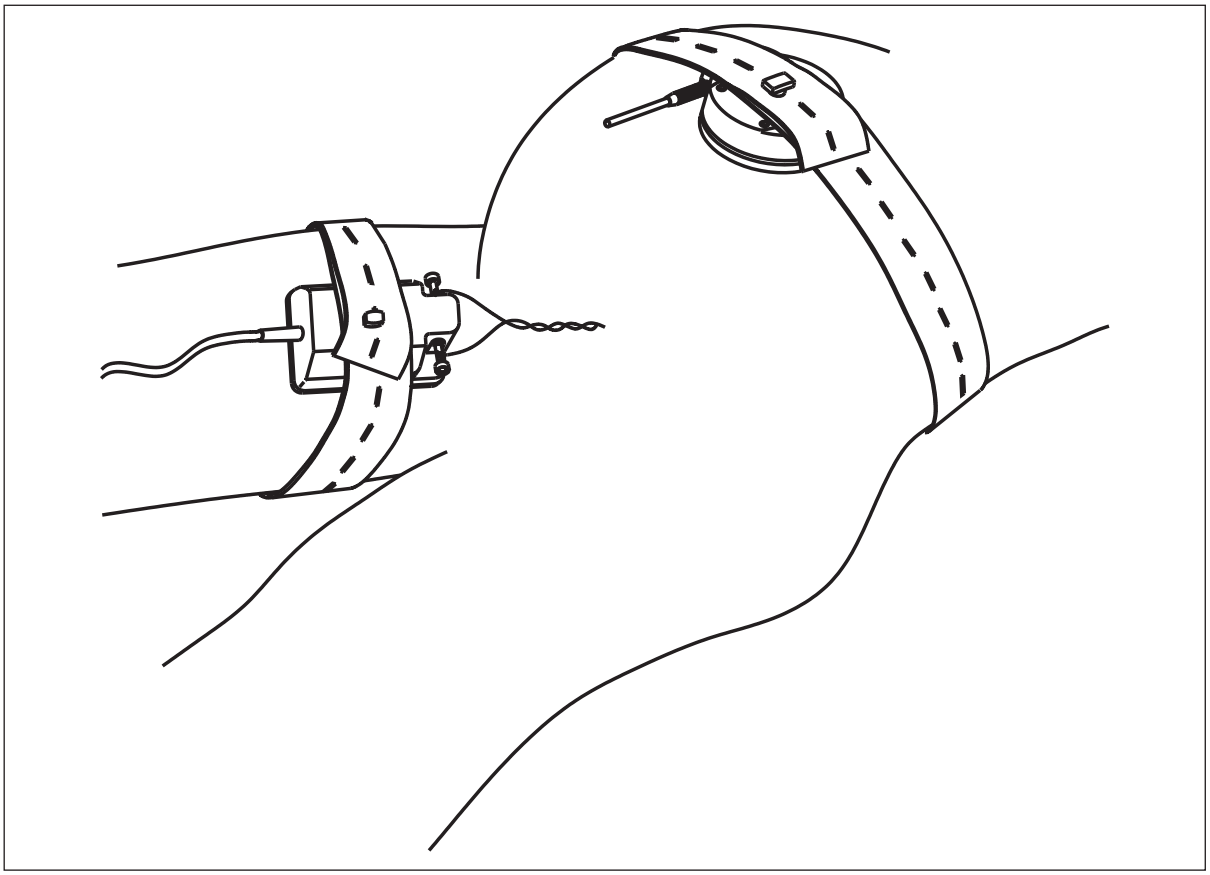
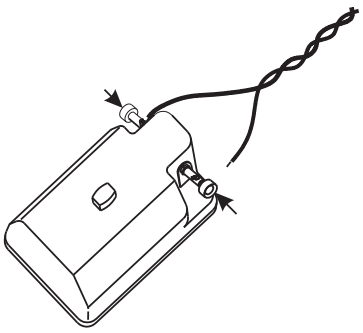


Figure 9 Leg Plate Positioning

Scalp Clip



The **BD4000** is compatible with all known makes of Fetal Scalp Electrodes. These are supplied separately, individually sterile wrapped for single use only. Before opening, inspect sterile pack carefully. If there is any breach of the sterile packing, the clip must be discarded. Using sterile technique, apply the scalp clip in accordance with the manufacturer's instructions.

Connect the scalp clip wires to the two terminals by depressing the spring loaded plunger, inserting the bared end of the wire into the opened side-entry slot and then releasing the plunger. Repeat for the second wire, connecting it to the other terminal. Check that the wires are securely held. Note that the wires can be connected either way round.

Allow the scalp clip/fetal connection to stabilise (this may take several minutes) and check for signal. A regular audio bleep at the fetal heart rate should be heard (adjust volume as required) and fetal heart rate should be displayed on the FHR display. Also, the fetal pulse indicator should flash with each detected pulse.

If signal quality is poor, check the scalp clip connections and the system wiring. Check that the transducer is firmly held in contact with the maternal thigh and, if necessary, re-apply the clip.

Leads-off Detector

If at any time contact is lost, after a short delay the text display will show 'CHECK LEADS'. Check all leg plate connections, maternal contact and scalp clip attachment. If necessary re-apply or replace clip.

Printing

Ensure sufficient paper is available in the paper tray. Initiate printing as for antepartum monitoring.

Trace Interpretation

This is beyond the scope of this document. It is assumed that the user is clinically qualified and experienced, both in the use of similar fetal monitoring equipment, the application of the clip and in interpreting the data provided.

As with antepartum monitoring, it must be recognised that FHR is just one indicator of fetal condition, which should be interpreted within an holistic approach to labour management.

As with any similar device, in poor/difficult signal conditions, false data may be displayed/printed. Additional educational material and support is available from Huntleigh Healthcare - contact your supplier for details.

After Use

The system should be carefully cleaned and decontaminated. Refer to Care of Your Baby Dopplex cleaning instructions for details.

Twins Monitoring

Equipment Set-up

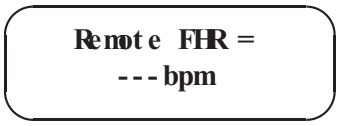
This requires two **BD4000** main units connected together to provide twins capability.

Please consult this User Manual.

Identify the 2x RS232 sockets on the rear panel, marked as shown.

Using the interface cable provided with the twins option pack, plug the femal plug (marked '1') into socket number ‘1’ on one of the units ensuring fixing screws are tightened securely. This unit will automatically be configured as the local unit.

The text display will show ‘Remote FHR =’ in the top line of the text display, with the remote unit’s FHR data displayed immediately below (shown as ‘- - - bpm’ with no signal).



Connect the other end, a male plug (marked ‘2’), to socket number ‘2’ on the second unit. This unit will automatically be configured as the remote unit. All controls on the remote unit will be disabled except for the volume control.

The remote unit display will read ‘Twins Remote Unit’.

The system is now automatically configured for twins operation.

CAUTION

If RS232 outputs 1 and 2 are used simultaneously, the system should comply with EN60601-1-1.

Any equipment connected to outputs 1 or 2 should comply with EN60601-1, EN60950, EN60065, EN60335 or EN61010.

Transducers/Operating Modes

2 Channel Fetal Heart Rate

The user can optionally use:

Ultrasound transducers on both local and remote units

Ultrasound on one (either) unit and FECG (scalp clip) on the other unit.

Connect the ultrasound transducers/leg plate as required, and set up on patient as normal.

☞ *The ultrasound signal quality indicator is not available in twins modes.*

When using the leg plate on either unit, a 'leads off', or poor contact, condition will be indicated on the local unit display as 'Check Leads'.

Contractions

Connect the contractions transducer to the 'local' unit and set up on the patient as normal. Note that the remote unit contractions function is disabled in twins mode.

Patient Event Marker

Connect to the 'local' unit. Note that the remote unit event marker function is disabled in twins mode.

Paper

In the local unit, optionally replace the standard paper pack with the special wide paper pack supplied with the Twins pack. (Refer to "**Paper Loading**" instructions).

The two FHR traces will then be printed separately on two separate full size FHR scales. A single contractions channel, slightly reduced in size is printed below the two FHR channels. The patient event marks will appear at the bottom of the lower FHR grid, while the clinical event marker and trace annotation text will appear above the top FHR grid. (See Fig. 10).

The two scales are labelled 'Local' and 'Remote'.

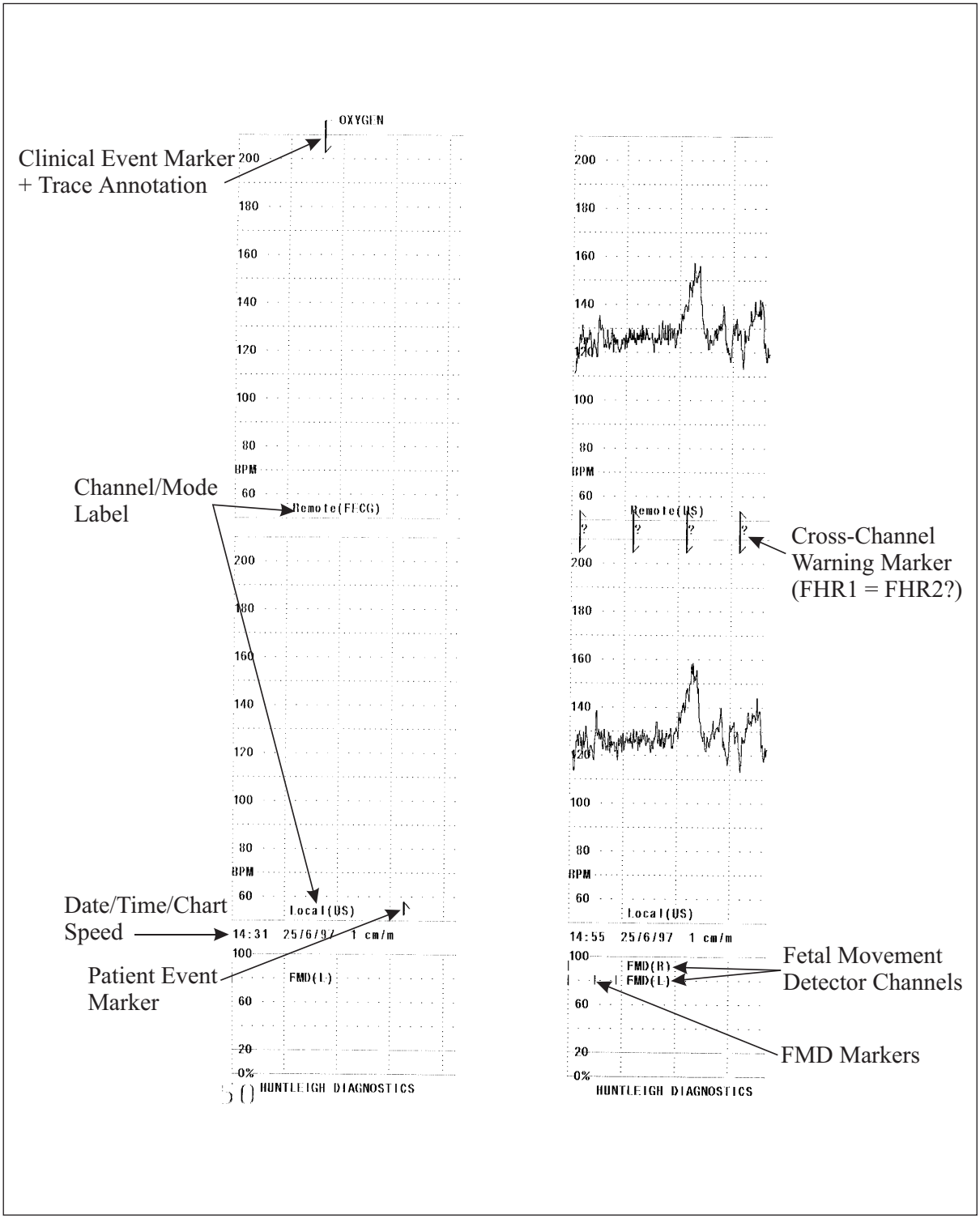


Figure 10 Twins Printout on Wide Paper

Alternatively, the standard paper can be used. The unit will automatically detect which paper width is installed and adjust the print-out accordingly. With standard paper, both traces will be superimposed on the standard FHR scale. The two traces will be labelled 'L' and 'R' at regular intervals to avoid confusion. (See Fig. 11).

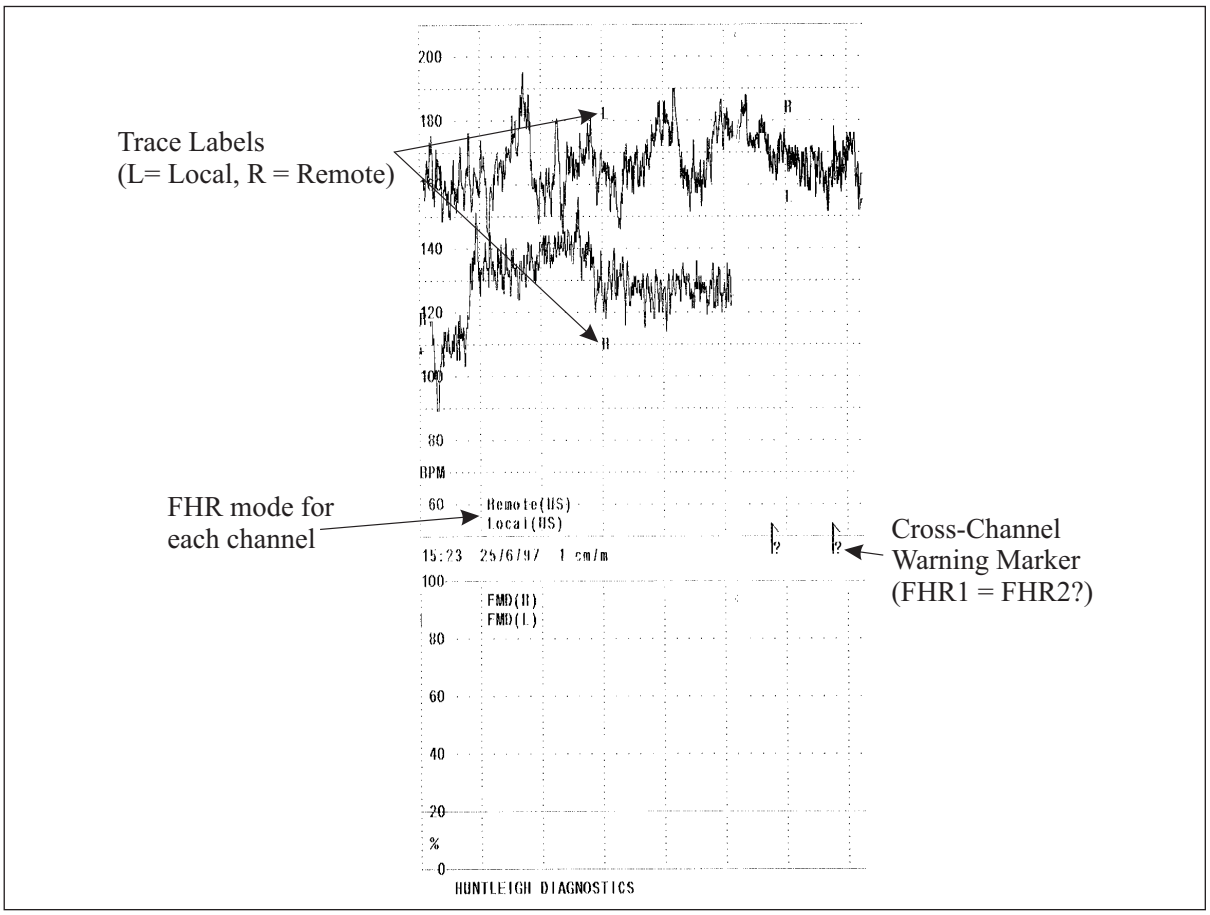


Figure 11 Twins Printout on Standard Paper

Printing

The twins system is now ready for recording twins. To commence monitoring, switch the local unit printer on, by pressing and releasing the printer On/Off button.

Cross-channel Warning

Check that different rate patterns are shown on the two traces. The system continuously checks for this also and will indicate '**FHR1 = FHR2**' if it detects the same data on both channels. In this event, simply reposition one of the ultrasound transducers to ensure that both twins are being separately monitored.

A marker ⌈? (or ⌈? on standard width paper) will also be printed on the paper.

Audio

When using ultrasound, separate audio sounds will be heard from each main unit. Adjust volume on each unit as required. Note that if one of the units is operating in FECG (scalp clip) mode, electronic bleeps will replace the Doppler heart sound in that unit.

External Data Input/Output

Electronic Viewing & Archiving systems

The **BD4000** can be connected to the Dopplex® Centrale electronic viewing and archiving system for real-time remote viewing and archiving of CTG data. Connection into this system is via an RS232 interface cable which would be included as part of the installation and commissioning of the Dopplex® Centrale system. For further details contact your supplier.

☞ *The BD4000 can also be configured via an extended set-up menu to interface with other makes of electronic viewing and archiving systems.*

Maternal Vital Signs monitoring

The **BD4000** can be connected to compatible Vital Signs Monitors (VSM) for including maternal data on the CTG print-out. A range of VSMs are supported.

As this is subject to change, this section will explain the operation of this feature in outline only. Technical data sheets are available from your supplier giving detailed information on specific makes/models of VSM.

Set-up:

Interface cables are specific to each make/model of external device. Ensure that your have the correct cable for your external device.

Simply plug the female end of the serial cable (labelled 'BD4000') into the serial port 1 on the rear panel of the **BD4000** and the other end into the external device.

☞ *Note that only one external device can be connected at a time. The second serial port on the BD4000 cannot be used for this application. This is reserved for out-going communication with electronic viewing and archiving system.*

Ensure that the **BD4000** is set-up to work with the connected external device - refer to Section 4 for system set-up details.

Operate the external device in accordance with the manufacturer's operating instructions.

Start the printer on the **BD4000** and the VSM data will be printed as configured. Alarm events triggered by the connected device will be reflected on the CTG print-out. See example print-out Figure 12 below, (note that printout details will vary depending on make/model of connected device).

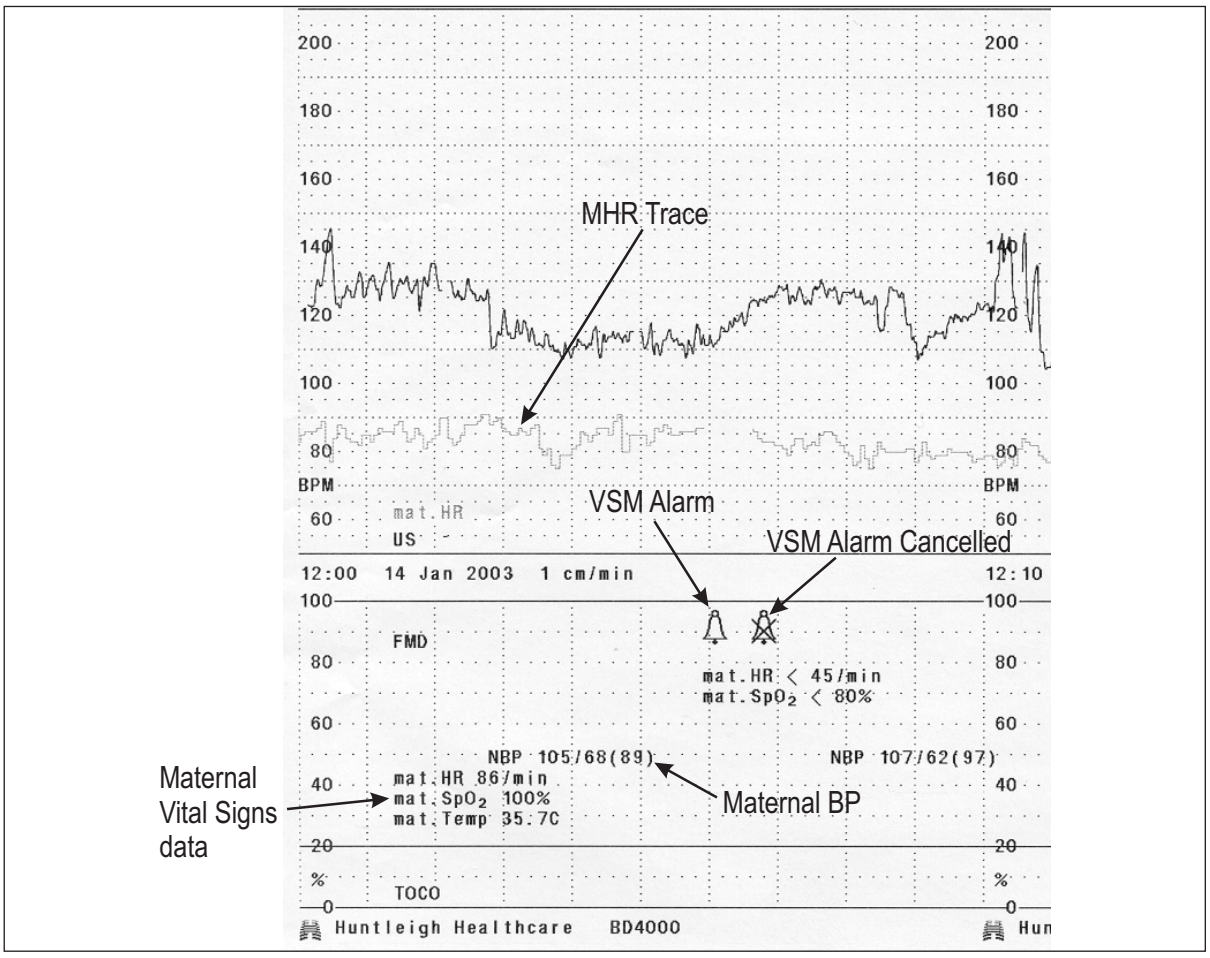


Figure 12 Vital Signs Monitoring sample printout

Fetal SpO_2 monitoring

The **BD4000** can be connected to a Fetal SpO_2 monitor for including $FSpO_2$ data on the CTG print-out. Currently the Nellcor® N400 is the only supported device. However, it is anticipated that other similar devices may be added in future software upgrades.
As this is subject to change, this section will explain the operation of this feature in outline only. Technical data sheets are available from your supplier giving detailed information on specific makes/models of Fetal SpO_2 monitors.

Set-up:

Interface cables are specific to each make/model of external device. Ensure that you have the correct cable for your external device.

Simply plug the female end of the serial cable (labelled 'BD4000') into the serial port 1 on the rear panel of the **BD4000** and the other end into the external device.

☞ *Note that only one external device can be connected at a time. The second serial port on the BD4000 cannot be used for this application. This is reserved for out-going communication with electronic viewing and archiving system.*

Ensure that the **BD4000** is set-up to work with the connected external device - refer to Section 4 for system set-up details.

Operate the external device in accordance with the manufacturer's operating instructions.

Start the printer on the **BD4000** and the Fetal $Sp0_2$ data will be printed as configured. Alarm events triggered by the connected device will be reflected on the CTG print-out. See example print-out Figure 13 below, (note that printout details will vary depending on make/model of connected device).

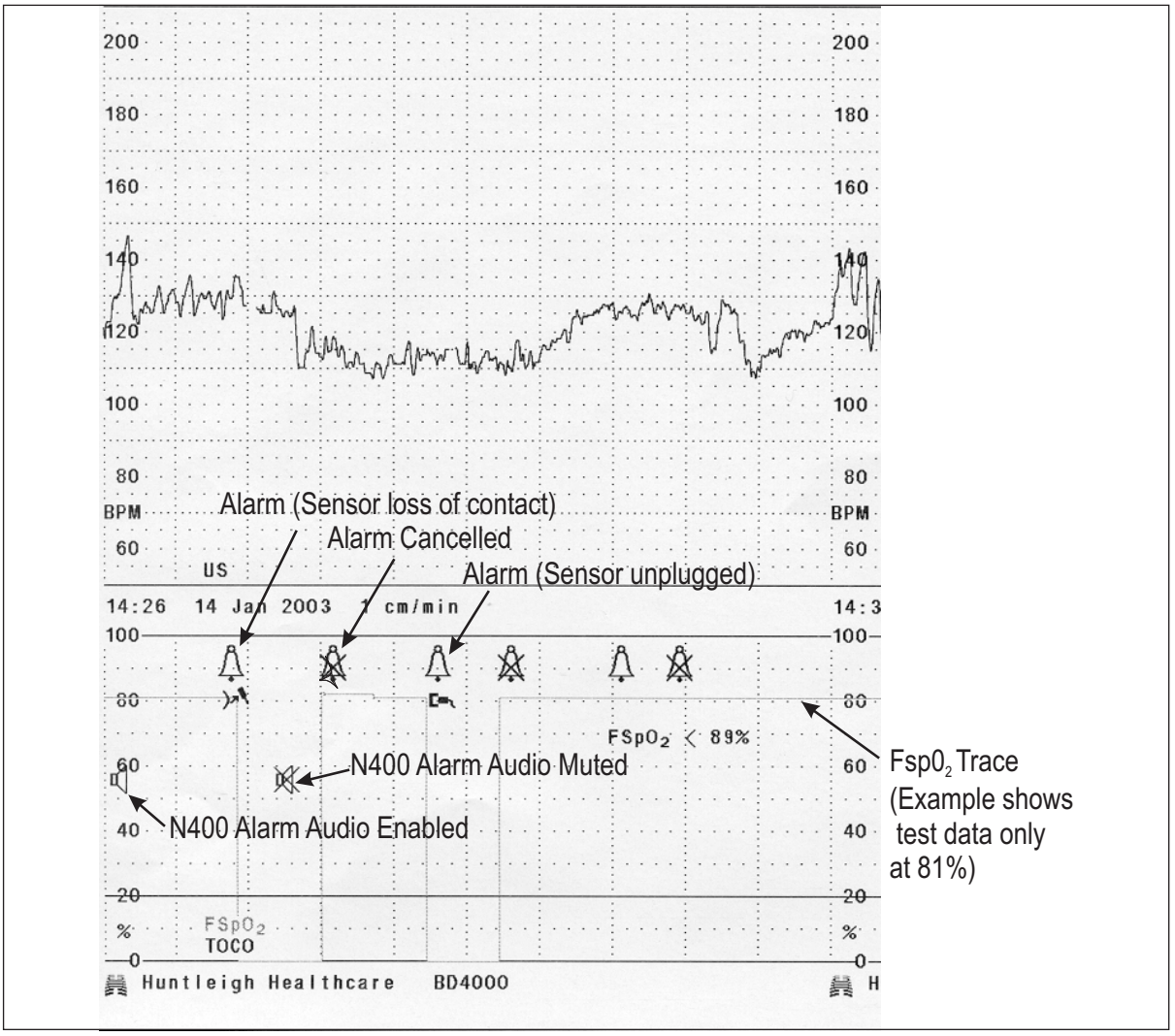


Figure 13 Fetal $Sp0_2$ sample printout

6. Care of your BD4000

Handling

Although the **BD4000** is robust and designed to withstand normal clinical use, the unit does contain delicate components and should be treated with care. This applies especially to the transducers and the active leg plate, which contain sensitive electronics and should not be dropped or knocked.

Maintenance

Other than careful cleaning, the **BD4000** does not require routine maintenance. If any parts of the system, particularly the leg plate, appear damaged in any way, the system should be returned to your local service centre for repair.

Ultrasound and ECG Coupling Gel

The use of water based gels supplied by Huntleigh Healthcare is strongly recommended. Oil based gels can damage the transducer and must not be used. The use of oil based gels will invalidate your warranty. The gels supplied are carefully designed for optimum performance in their intended uses. It is important to use the correct gels for each application to ensure best performance.

CAUTION

Switch the unit off and disconnect from the mains before cleaning.

WARNING

The BD4000 and its range of options and accessories are not designed to be sterilised.

FECG scalp clips are normally supplied sterile for <u>single use only</u>

Cleaning

Main Unit

If required, this can be wiped with a soft cloth dampened with a mild detergent solution, avoiding the connectors. Do not allow any fluid to seep into the unit. Ensure the unit is completely dry before reconnecting to the mains.

Ultrasound Transducer and FECG Leg Plate	These should be cleaned by immersing in warm (50°C max.), mild detergent solution, using a bottle brush if necessary. Do not soak, or run under a tap. Rinse with clean water and dry thoroughly before use.

WARNING

Do NOT immerse connectors

Contractions Transducer (TOCO)	Wipe with a soft cloth dampened with a mild detergent solution, avoiding the connector. Do not allow any fluid to seep into the transducer. Dry thoroughly before use.
Transducer Belts	These should be hand-washed at 40°C max., using a mild detergent solution. Rinse with clean water and dry thoroughly (without using heat) before use.

Disinfection

Transducers and Leg Plate (LP1) Only.

To assist with disinfection, wipe the transducers and leg plate with a soft cloth dampened with a sodium hypochlorite 1000ppm solution, and wipe dry. Please be sure to check your local infection control policies or equipment cleaning procedures.

CAUTION

Phenolic, detergent based disinfectants containing cationic surfactants, ammonia based compounds, or antiseptic solutions such as Steriscol or Hibiscrub should never be used on any part of the system as permanent damage will result.

7. Troubleshooting

If you encounter difficulties in operating your **BD4000** fetal monitor, the following table lists some possible causes and solutions.

Problem	Cause	Solution
Poor signal (U/S)	Fetus moved or transducer incorrectly positioned. Insufficient gel.	Reposition transducer. Apply gel.
Poor signal (FECG)	Poor scalp clip attachment. Poor leg plate maternal contact - belt loose or insufficient ECG gel. Poor connections.	Re-apply or replace scalp clip. Adjust belt. Apply ECG gel. Check connections.
UA display shows 'L' or 'H'	Toco transducer too loose ('L')or tight ('H').	Check and adjust belt. Re-zero using control panel zero button.
Paper feeds but no printing	Paper installed upside down.	Re-install paper pack with sensitive side up.
Paper not feeding	Paper tray not fully shut. Out of paper. Paper jammed.	Push firmly in at both ends of tray - ensure both latches are locked in. Check paper. Check correct pack installed. Ensure top and bottom packing cards are removed.
Print quality poor	Paper tray not latched shut at one end or both ends.	Push firmly in at both ends of tray - ensure both latches are locked in.

If trouble persists, consult your service centre.

CAUTION

This product contains sensitive electronics, therefore strong radiated radio frequency signals could possibly interfere with it. This will be indicated by unusual sounds from the loudspeaker.

This should not affect the CTG.
However, we recommend that the source of interference is identified and eliminated.

8. Warranty and Service

Warranty

Huntleigh Healthcare's standard terms and conditions apply to all sales. A copy is available on request. These contain full details of warranty terms and do not limit the statutory rights of the customer.

Service Returns

For service, maintenance and any questions regarding this, or any other Huntleigh Healthcare Dopplex product, please contact:

Huntleigh Healthcare Ltd - Diagnostic Products Division,
35, Portmanmoor Rd.,
Cardiff. CF24 5HN
United Kingdom.

Tel: +44 (0)29 20496793 - Service (24hr answer machine)
email: service@huntleigh-diagnostics.co.uk

Tel: +44 (0)29 20485885 - Customer Care

Fax: +44 (0)29 20492520

or your local supplier.

CAUTION

In the unlikely event that you need to return this product, please adopt local decontamination procedures and provide documentation outlining the product's status.
Please ensure that this documentation is accessible without having to open the package.

Huntleigh Healthcare Ltd reserves the right to return, unopened, any shipment not complying with this requirement.

9. Technical Data

General

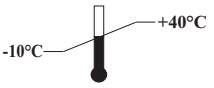
Product Name: **Baby DOPPLEX® 4000**
Model No.: **BD4000**

Physical

Size - Control Unit: 93mm x 380mm x 250mm (HxWxD)
Weight : 4.5Kg

Environmental

Operating Temperature: +10°C to +30°C
Storage Temperature : -10°C to +40°C



Electrical

Power Supply: 100 to 250Va.c. 50/60Hz
Fuse Type : T2A 250V
Audio Power: 1 Watt max.

Ultrasound Transducer

Transmitter Frequency: US1 - 1.5MHz ± 1%

Acoustic Output: Under the requirements laid down in IEC1157: 1992, the peak negative acoustic pressure does not exceed 1MPa. The output beam intensity does not exceed 20mW/cm² and the spatial-peak temporal-average intensity does not exceed 100mW/cm².

Contractions Transducer

Range: 0 to 100% relative units.
Max. Load: 300g.

Regulatory Compliance/Standards

Complies with: BS5724 : Part 1 : 1989
IEC601-1 : 1988
EN60601-1 : 1990

EN60601-1 Classification: Type of shock protection - Type B

except Leg Plate (LP1) - Type BF

Degree of Protection Against Water Ingress: Ordinary equipment except: Leg plate (LP1 & LP2) - IP67.

Degree of Safety in Presence of Flammable Gases: Not suitable for use in the presence of flammable gases.

Mode of Operation: Continuous

Performance

FHR Range:	U/S - 50 to 210 bpm FECG - 30 to 240 bpm
FHR Accuracy:	±1bpm over full range.
FHR Scale Options:	50 to 210 bpm at 20 bpm/cm, 30 to 240 bpm at 30 bpm/cm.

Addendum 1- IntraUterine Pressure Option

Introduction

This addendum details the procedure for IntraUterine Pressure (**IUP**) monitoring using the optional **IUP** interface module and suitable sensor system in conjunction with the **Baby Dopplex® 4000 (BD4000)**.

This addendum should be read in conjunction with the BD4000 user manual.

It is assumed that the user is familiar with the use of the BD4000 and experienced in normal fetal monitoring practice.

IUP is an invasive procedure and must only be performed by suitably qualified practicing clinicians.

IUP monitoring should be discontinued when 2nd stage labour commences, as the data will no longer be accurate due to maternal bearing down

IntraUterine Pressure monitoring provides a more accurate method of monitoring maternal contractions, or uterine activity, than conventional external tocography.

External tocography provides a relative, indirect indication of uterine activity. IntraUterine pressure monitoring provides a more direct, absolute measure of contractions by monitoring the amniotic fluid pressure inside the uterus. The output is calibrated in user selectable options of millimetres of Mercury (mmHg) or kiloPascals (kPa).

Description

The **IUP** option kit comprises:

IUP interface module

IUP module trolley bracket kit

Sensor connecting lead*

Sensor system*

☞ ** In certain markets only - these are usually centrally sourced by hospitals from their preferred supplier.*

This kit is used in conjunction with the **BD4000** to provide a full **IUP** monitoring capability.

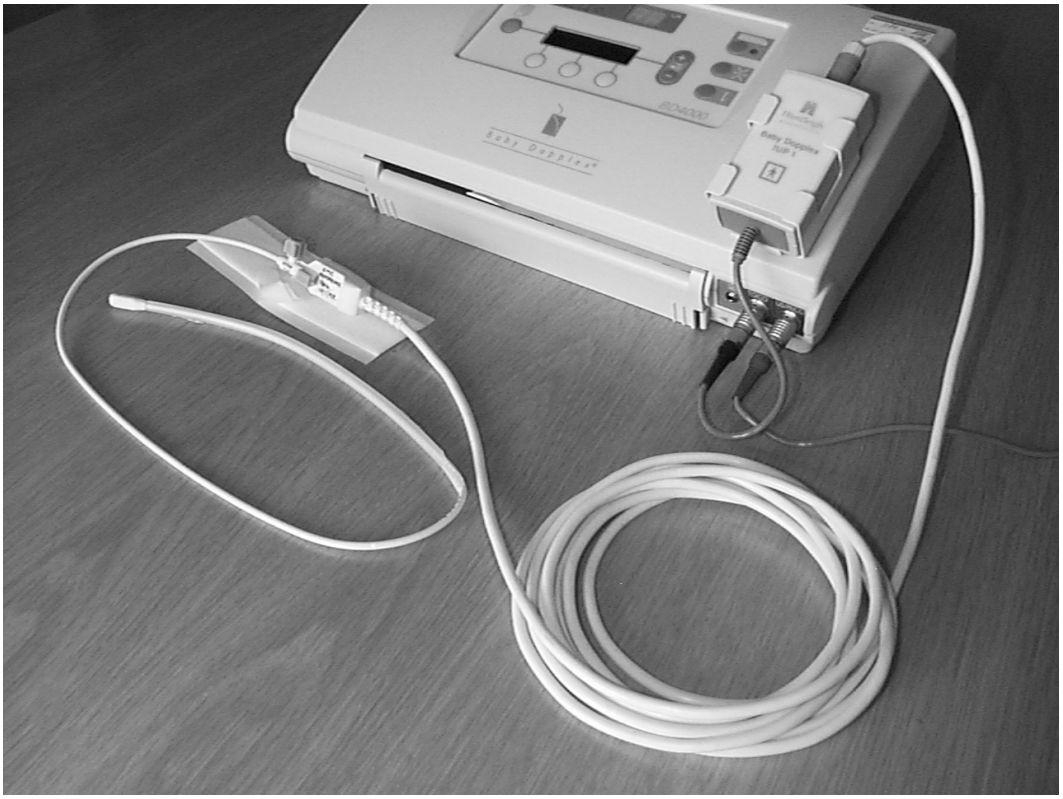


Figure 1 - IUP system installed with Sensortip™ probe connected

IUP Interface Module

This interface module provides an electronic interface between the sensor and the **BD4000** main unit.

WARNING

This module provides the necessary additional electrical isolation required for this invasive application (type before).
Under no circumstances must any attempt be made to connect the sensor directly to the main unit, or in any way to bypass this module.

The attached connecting lead plugs into the **BD4000** main unit in place of the external contractions transducer (see Fig. 1).

The sensor, or sensor interface lead (depending on sensor type used), plugs into the integral socket on the end panel of the **IUP** module (see Fig. 1).

IUP Module Trolley Bracket Kit

It is recommended that the **BD4000** monitor is mounted on its trolley. A bracket kit is provided with the **IUP** kit to enable the **IUP** module to be mounted alongside the monitor on the trolley (see Fig. 2).

Refer to Fig. 4 for assembly instructions.

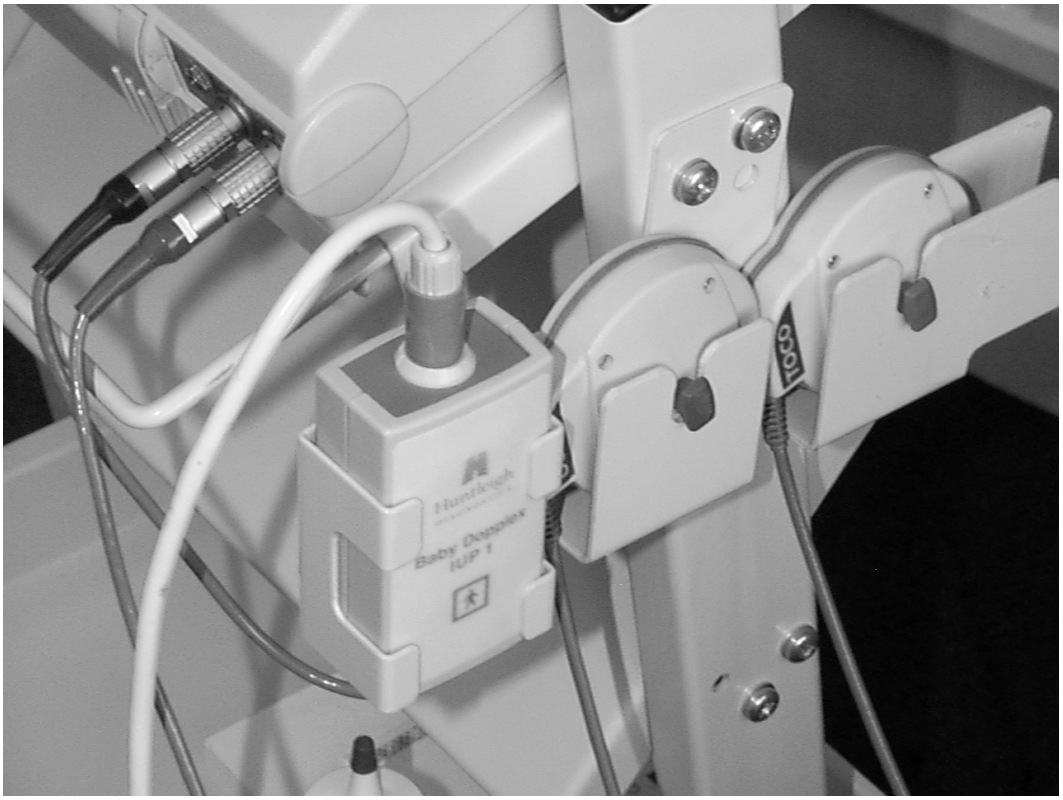


Figure 2 - IUP module installed on trolley

Alternatively, adhesive pads are provided to allow the **IUP** mounting bracket to mounted directly onto the **BD4000** case (see Figs. 1 & 3).

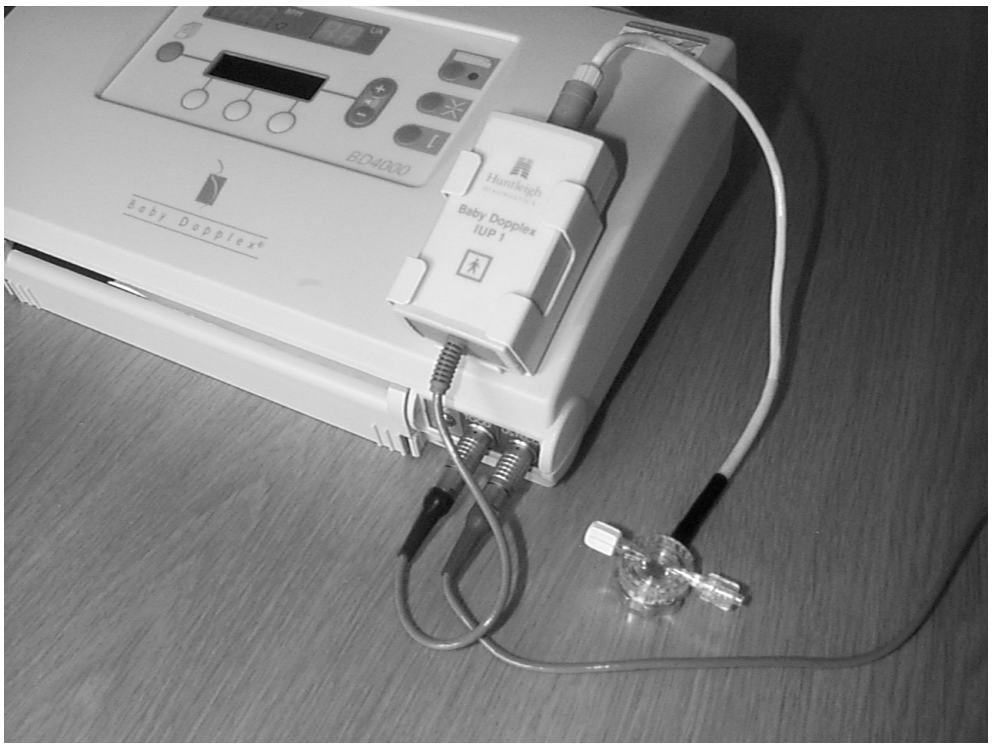


Figure 3 - Mounting IUP module on BD4000,
External Sensor + Pressure Dome

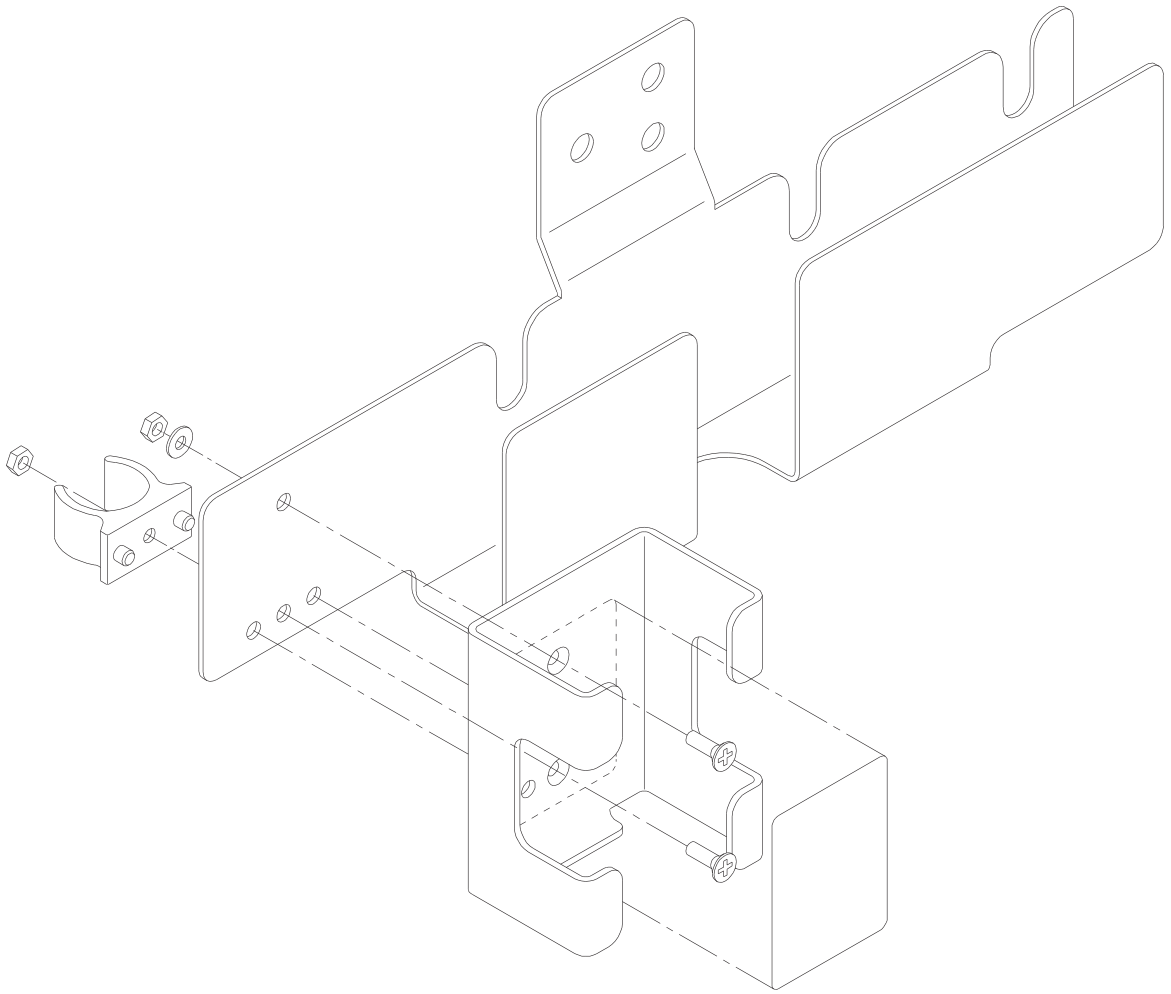


Figure 4 - Mounting Bracket Assembly

Sensor System There are two types in general use - external (see Fig. 3) and internal (see Fig 1).

External External sensor systems use an external physiological pressure transducer, connected to a fluid filled catheter system, via a pressure dome. The catheter is inserted into the uterus, intrauterine fluid pressure being measured remotely (i.e. external to the patient) through the fluid column in the catheter.

☞ *To eliminate hydrostatic errors, the external sensor must be positioned at the same height as the tip of the catheter. The system must be zeroed before insertion.*

Caution

The sensor, which plugs directly into the IUP module, is reusable, but the catheter and pressure dome are single use components.

Internal

Internal sensors have the sensing element integrated into the tip of the catheter. This is much simpler to set up and use and there is no hydrostatic effect.

The external end of the catheter includes a 'zero' port to allow calibration after insertion and an electrical connector to connect to a reuseable interface lead.

Caution

This type of sensor is intended for single patient use only.

Caution

These pressure sensors are precision instruments, they must be handled with care at all times, in accordance with the manufacturer's instructions.

Huntleigh Healthcare do not manufacture **IUP** sensor systems. The **BD4000 IUP** system is compatible with a range of both external and internal sensor systems currently available from independent sensor suppliers. Existing users will already have an established preferred sensor type sourced centrally by the hospital.

For more information on sensor suppliers contact your dealer. Interface leads to suit a range of sensor systems are available either from the sensor supplier or directly from Huntleigh Healthcare.

System Set-up

Before use, inspect the monitor, **IUP** module and other components for damage. Do not proceed if any damage is suspected.

1. Prepare the **BD4000** for use in accordance with the user manual instructions.
2. In the user set up menu, select the preferred **IUP** units (options: mmHg or kPa selected by pressing softkey 1or 3). The printed uterine activity (UA) scale and the UA display will be calibrated in the selected units.

☞ *TWINS - For twins monitoring, the* IUP *module must be connected to the 'local' unit NOT the 'remote' unit (refer to BD4000 user manual for details).*

3. Mount the **IUP** module in its bracket.

4. Plug the cable from the **IUP** module into the contractions socket ('Toco' - colour coded blue) on the monitor.

Sensor Set-up:

5. **External Sensor**:
   a) Plug the lead attached to the physiological pressure sensor into the socket on the **IUP** module (colour coded yellow).
   b) Using sterile technique, connect the pressure dome to the sensor in accordance with the manufacturer's instructions.
   c) Connect the catheter to the pressure dome in accordance with the manufacturer's instructions.
   d) Through the pressure dome ports, fill the catheter with fluid (e.g. Saline) and purge the system of air.
   e) Zero the system to atmospheric pressure by holding the catheter tip level with the sensor and pressing the contractions zero button on the monitor.
   f) Insert the catheter in accordance with the manufacturer's instructions.
   g) The system is now ready for monitoring.

6. **Internal Sensor**:
   a) Plug the correct interface lead (depending on sensor make), into the socket on the **IUP** module (colour coded yellow).
   b) Using sterile technique, connect the sensor to the interface cable connector.
   c) Zero the system in accordance with the manufacturer's instructions in conjunction with the contraction zero push button on the **BD4000**.
   d) Insert the catheter in accordance with the manufacturer's instructions.
   e) The system is now ready for monitoring.

7. Proceed with monitoring as required.

8. After each use, dispose of the sensor /catheter single use items and clean the system as described under Cleaning.

If any doubt exists at any time during the trial, uterine activity should be confirmed by palpation or other means.

Handling & Maintenance

There are no special maintenance requirements for the reusable parts of the **IUP** system, beyond inspection for damage and cleaning after each use.

Cleaning

Between each use, the system must be cleaned in accordance with local infection control procedures.

IUP Module

If required, this can be wiped with a soft cloth dampened with a mild detergent solution, avoiding the connectors. Do not allow any fluid to seep into the unit. Ensure it is completely dry before reconnecting.

Interface cables

Isopropyl based alcohol swabs are recommended for cleaning the interface cables.

Disinfection

IUP Module

To assist with disinfection, the module can be wiped with a soft cloth dampened with a sodium hypochlorite 1000ppm solution, and wiped dry.

Interface cables

Isopropyl based alcohol swabs are recommended to assist in disinfecting the interface cables.

Caution

Phenolic, detergent based disinfectants containing cationic surfactants, ammonia based compounds, or antiseptic solutions such as Steriscol or Hibiscrub should never be used on any part of the system as permanent damage will result.

WARNING

The IUP module, interface cables and external pressure sensors are not designed to be sterilised.

Technical Data

Performance

Range	Display -9 to +99mmHg or -1 to +13kPa System -50 to +300mmHg, or - 6.7 to +40 kPa
Resolution	Display 1mmHg or kPa Printer 1mmHg or 0.13 kPa
Accuracy	1% of FSD

Sensor Interface

Excitation Voltage	5 V d.c.
Nominal sensor impedance	1K

Sensitivity

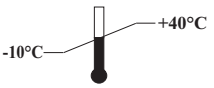
Input sensitivity	25 μV/mmHg

IEC 601-1 Classification

Degree of shock protection	Type BF
Protection against water ingress	Ordinary equipment
Degree of safety in presence of flammable anaesthetics	Not suitable for use in presence of flammable anaesthetics
Mode of operation	Continuous

Environmental

Operating temperature (module)	+10°C to +30°C
Storage temperature	-10°C to +40°C



Appendum 2 - FECG Inteface Module (LP2)

Upgrade Options

The following additional options may have been supplied with your unit or can be ordered separately to upgrade your unit:

Intrapartum upgrade

Contains:

FECG Interface Module (LP2)

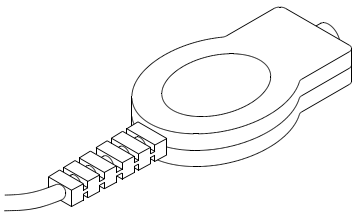
Leg plate interface cable.

Intrapartum Operation

For external ultrasound monitoring refer to the “Antepartum Operation” section.

Connecting the Transducers

Leg Plate Interface Cable



Plug the FECG interface module (marked ‘LP2’, connector colour coded red) into the ‘US/FECG’ socket, also colour coded red on the main unit, in place of the ultrasound transducer.

This automatically reconfigures the system for intrapartum operation.

The display will show **FECG** in the top right corner.

Insert the Leg plate interface cable plug (colour coded green) into the green socket on the FECG interface module (LP2), refer to Figure 1.

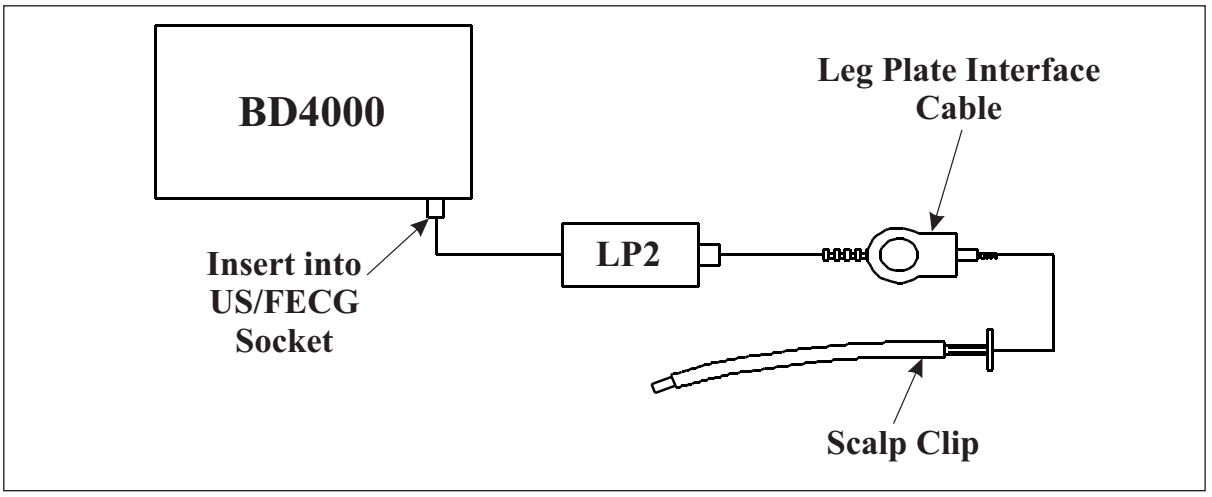


Figure 1 LP2 & Scalp Clip Connection

The signal quality indicator is disabled in FECG mode. However, a ‘Leads Off’ indicator will detect loss of FECG signal.

Contractions Transducer

Connect as for antepartum operation - refer to Antepartum Operation section.

WARNING

The FECG interface module contains sensitive electronics and provides the additional electrical isolation (type BF) required for safe connection to the fetus. Inspect carefully before use for any damage as this may affect electrical isolation.

Intra Uterine Pressure (IUP) Monitoring Option

For use in intrapartum monitoring instead of the external contractions transducer. For set-up and operation, refer to the instructions supplied with the IUP option pack.

Patient Event Marker

If required, connect as for antepartum operation - refer to Antepartum Operation section.

Fetal Movement Detector

This is intended for antenal use and should be disabled during labour monitoring (refer to “System Configuration” section). It is automatically disabled in FECG mode.

The unit is now ready for use.

Monitoring

Leg Plate

Secure the leg plate on the thigh using an attachment pad, with the cable leading down towards the feet as shown below in Figure 2.

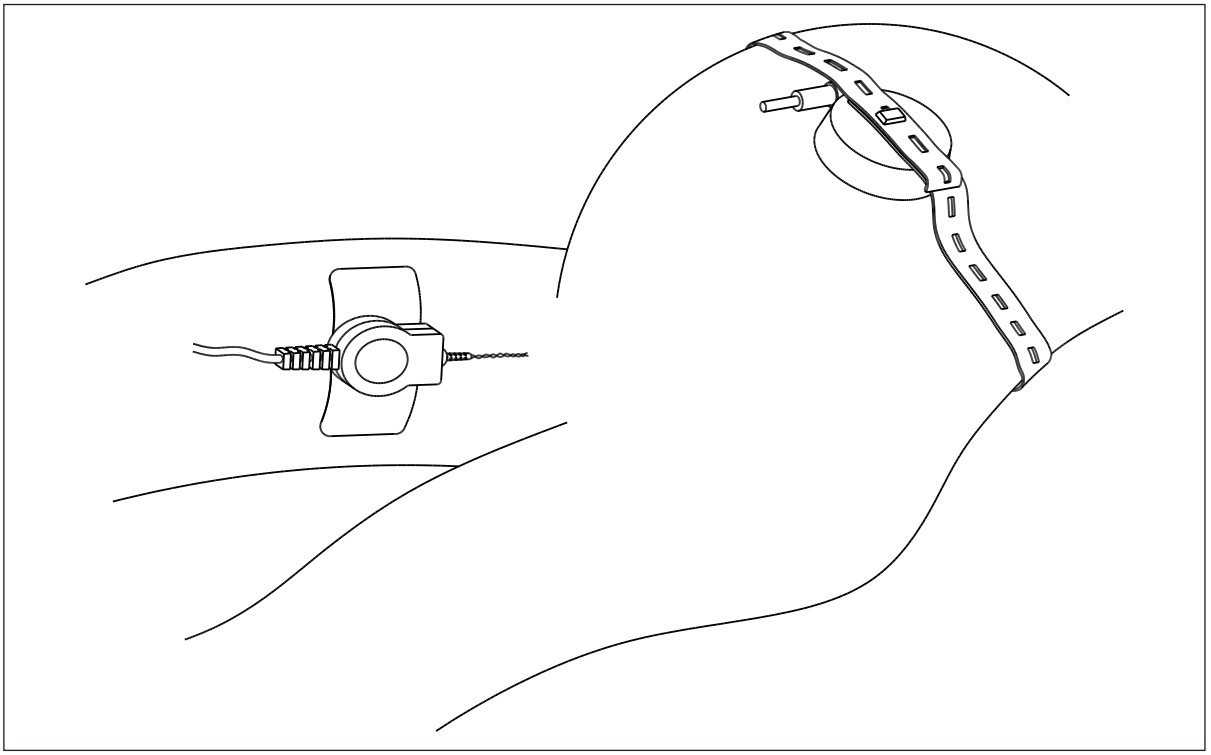
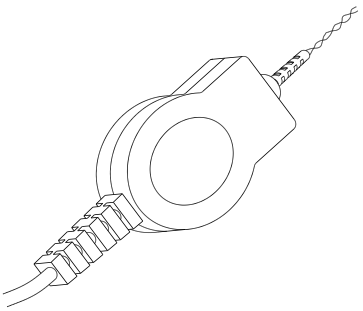


Figure 2 Leg Plate Positioning

Scalp Electrode

The **BD4000** is designed for use with the **Corometrics** Qwik Connect Plus spiral electrode. These and the legplate attachment pads are supplied separately, individually sterile wrapped for single use only. Before opening, inspect sterile pack carefully. If there is any breach of the sterile packing, the electrode must be discarded. Using sterile technique, apply the scalp electrode in accordance with the manufacturer's instructions.

Plug the scalp electrode connector into the leg plate socket. (See Fig. 2).



Allow the scalp electrode/fetal connection to stabilize (this may take several minutes) and check for signal.
A regular audio beep at the fetal heart rate should be heard (adjust volume as required) and fetal heart rate should be displayed on the FHR display. Also, the fetal pulse indicator should flash with each detected pulse.

If signal quality is poor, check the scalp electrode connections and the system wiring. Check that the transducer is firmly held in contact with the maternal thigh and, if necessary, re-apply the electrode.

Leads-off Detector

If at any time contact is lost, after a short delay the text display will show 'CHECK LEADS'. Check all leg plate connections, maternal contact and scalp electrode attachment. If necessary re-apply or replace electrode.

Printing

Ensure sufficient paper is available in the paper tray. Initiate printing as for antepartum monitoring.

Trace Interpretation

This is beyond the scope of this document. It is assumed that the user is clinically qualified and experienced, both in the use of similar fetal monitoring equipment, the application of the electrode and in interpreting the data provided.

As with antepartum monitoring, it must be recognized that FHR is just one indicator of fetal condition, which should be interpreted within an holistic approach to labour management.

As with any similar device, in poor/difficult signal conditions, false data may be displayed/printed. Additional educational material and support is available from Huntleigh Healthcare.

Handling

Although the **BD4000** is robust and designed to withstand normal clinical use, the unit does contain delicate components and should be treated with care. This applies especially to the transducers and the FECG interface module, which contain sensitive electronics and should not be dropped or knocked.

Maintenance

Other than careful cleaning, the **BD4000** does not require routine maintenance. If any parts of the system appear damaged, in any way, the system should be returned to your local service centre for repair.

Ultrasound and ECG Coupling Gel

The use of water based gels supplied by Huntleigh Healthcare is strongly recommended. Oil based gels can damage the transducer and must not be used. The use of oil based gels will invalidate your warranty. The gels supplied are carefully designed for optimum performance in their intended uses. It is important to use the correct gels for each application to ensure best performance.

CAUTION

Switch the unit off and disconnect from the electrical outlet before cleaning.

WARNING

The BD4000 and its range of options and accessories are not designed to be sterilised.

FECG scalp electrodes are normally supplied sterile for single use only.

Cleaning

Main Unit

If required, this can be wiped with a soft cloth dampened with a mild detergent solution, avoiding the connectors. Do not allow any fluid to seep into the unit. Ensure the unit is completely dry before reconnecting to the electrical outlet.

Ultrasound Transducer

This should be cleaned by immersing in warm (50°C max.), mild detergent solution, using a bottle brush if necessary. Do not soak or run under a tap. Rinse with clean water and dry thoroughly before use.

WARNING

Do NOT immerse connectors

FECG interface module, legplate interface cable and Contractions Transducer (TOCO)	Wipe with a soft cloth dampened with a mild detergent solution, avoiding the connector. Do not allow any fluid to seep into the transducer. Dry thoroughly before use.
Transducer Belts	These should be hand-washed at 40°C max., using a mild detergent solution. Rinse with clean water and dry thoroughly (without using heat) before use.

Disinfection

Transducers and Leg Plate interface cable.

To assist with disinfection, wipe the transducers and leg plate with a soft cloth dampened with a sodium hypochlorite 1000ppm solution (2oz bleach per each gallon of water), and wipe dry.

Please be sure to check your local infection control policies or equipment cleaning procedures.

CAUTION

Phenolic, detergent based disinfectants containing cationic surfactants, ammonia based compounds, or antiseptic solutions such as Steriscol or Hibiscrub should never be used on any part of the system as permanent damage will result.

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Medical Devices Directive 93/42/EEC

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